UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA,
THE STATE OF CALIFORNIA,
THE STATE OF COLORADO,
THE STATE OF CONNECTICUT,
THE STATE OF DELAWARE,
THE DISTRICT OF COLUMBIA,
THE STATE OF FLORIDA,
THE STATE OF GEORGIA,
THE STATE OF HAWAII,
THE STATE OF ILLINOIS,
THE STATE OF INDIANA,
THE STATE OF IOWA,
THE STATE OF LOUISIANA,
THE STATE OF MARYLAND,
THE COM. OF MASSACHUSETTS,
THE STATE OF MICHIGAN,
THE STATE OF MINNESOTA,
THE STATE OF MONTANA,
THE STATE OF NEVADA,
THE STATE OF NEW JERSEY,
THE STATE OF NEW MEXICO,
THE STATE OF NEW YORK,
THE STATE OF NORTH CAROLINA,
THE STATE OF OKLAHOMA,
THE STATE OF RHODE ISLAND,
THE STATE OF TENNESSEE,
THE STATE OF TEXAS,
THE STATE OF VERMONT,
THE COM. OF VIRGINIA, and
THE STATE OF WASHINGTON
ex rel. [UNDER SEAL],

Plaintiffs,

v.

[UNDER SEAL],

Defendant.

UNDER SEAL

Qui tam action filed in camera and under seal in accordance with 31 U.S.C. § 3730(b)(2)

Civil Action No. _____

COMPLAINT

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THE STATE OF WASHINGTON
ex rel. J. DOE,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

UNDER SEAL

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1. Plaintiff relator J. Doe brings this action on behalf of the United States of America as well as the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Vermont, the Commonwealth of Virginia, and the State of Washington (collectively, the "Plaintiff States") against Janssen Biotech, Inc. ("Janssen" or "the Company") for violations of the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "Federal FCA"), and the Plaintiff States' false claims statutes (collectively, the "State FCAs") to recover all damages, civil penalties and all other recoveries provided for under these statutes.

I. INTRODUCTION

2. Medicare and Medicaid rely upon treatment providers to exercise independent judgment and focus solely on the best interests of the patients in making treatment decisions. When a physician selects a treatment course because of some personal financial benefit, that decision is not necessarily in the patient's best interests. Kickback schemes corrupt the integrity of every treatment decision influenced by the scheme because remuneration given to those who make such decisions frequently results in a drug or service being provided that is medically unnecessary, less effective than other drugs or services, of poor quality, and/or harmful to a vulnerable patient population.

3. To protect patients and the government health care programs from the corrupting influence of inappropriate compensation provided to medical providers, the federal government enacted the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "Federal AKS"), which prohibits the payment of kickbacks in any form to providers who treat patients insured by a federal health care program. Like the federal government, most of the Plaintiff States have also enacted anti-kickback statutes (collectively, the "State AKS").

4. In addition, falsely certifying compliance with the Federal AKS in connection with claims submitted to a federal health care program is actionable under the Federal FCA. Similarly, falsely certifying compliance with the Federal AKS and State AKS in connection with claims submitted to the state-administered Medicaid programs is likewise actionable under the State FCAs.

5. The Federal and State FCA violations alleged herein arise from Janssen's long-running nationwide kickback scheme that the Company has been using to induce health care providers to prescribe and administer via infusion two different biologic therapy drugs, Remicade and Simponi ARIA, to patients, many of whom are Medicare and Medicaid beneficiaries, with rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis or other diseases. Janssen's kickbacks are in the form of valuable business advisory services that the Company regularly provides free of charge to rheumatology and gastroenterology practices throughout the country to help the practices establish infusion suites (so the practices will directly administer Remicade and Simponi ARIA infusions) and then, once opened, to help the practices operate the infusion businesses more efficiently and profitably (so the practices grow their infusion business by prescribing and infusing more Remicade and/or Simponi ARIA). These practice management services that Janssen provides to its top

rheumatology and gastroenterology practice accounts carry significant value, as demonstrated by the positive impact the services have on the physician practices and as also demonstrated by the normal market price of these services – over $1,200 per consultative session.

6. Janssen effectively becomes a business partner to rheumatology and gastroenterology practices, helping these practices establish, operate and grow their infusion business so they continue using and buying Remicade and Simponi ARIA. In fact, Janssen tells the rheumatology and gastroenterology practices that "we want to partner with you in your infusion business operations to help make your infusion service line seamless." Janssen employs this corruptive and illegal strategy because when physician practices are invested in and profiting from infusion services they desire and indeed become reliant upon the substantial revenue received from infusing Remicade and Simponi ARIA, which they cannot obtain by prescribing competing drugs that the patients can self-administer at home.

7. Janssen's free practice management and business advisory services help rheumatology and gastroenterology practices by educating and advising them how to grow and how to maximize the revenue from their infusion business while lowering their overhead costs. This in turn induces the practices to continue prescribing and infusing Janssen's products rather than less lucrative biologic drugs that are delivered more conveniently (and less expensively) through subcutaneous injection or through tablets. As such, Janssen's kickback scheme has induced hundreds if not thousands of health care providers to disregard their patients' best interests and self-servingly prescribe and administer Remicade and Simponi ARIA infusion therapy to patients, including Medicare and Medicaid beneficiaries, in order to maximize the profit from their infusion businesses. This scheme has been corrupting rheumatologists' and gastroenterologists' treatment decisions for more than ten years and has correspondingly caused

the federal and state governments to pay for countless Remicade and Simponi ARIA infusion treatments tainted by Janssen's illegal marketing scheme. Janssen's kickback scheme has helped the Company generate billions of dollars in sales of Remicade and Simponi ARIA – including annual sales of over $1 billion from the treatment of approximately 60,000 Medicare beneficiaries (making it one of Medicare's top expenses). The federal and state governments have paid hundreds of millions of dollars to physician practices for infusion services that were never entitled to reimbursement.

8. In addition to the substantial economic harm caused to the public fisc, Janssen's scheme also harms unsuspecting patients who are suffering from rheumatoid arthritis, Crohn's disease, ulcerative colitis or other painful and often debilitating diseases. Janssen is knowingly causing physicians to disregard the patients' best interests by inducing the physicians to prescribe a biologic treatment that requires the patients to travel to an infusion suite – which Janssen helped establish and effectively helps operate – every eight weeks to sit for a two-hour infusion (Remicade) or 30-minute infusion (Simponi ARIA) instead of prescribing a less-profitable biologic drug that may be more effective and appropriate for the patient and can be self-administered in minutes in the comfort and privacy of the patient's home. These patients are undergoing Remicade and Simponi ARIA infusions as a result of orders from health care providers that are based on undisclosed financial, rather than independent clinical, considerations.

9. Although Janssen knows, as its own internal documents show, that the Federal AKS and State AKS prohibit it from providing business advisory and practice management services for free to providers to induce them to prescribe and infuse its drugs, it has been disregarding these laws for more than ten years, choosing instead to put sales growth and profits

ahead of its duty to comply with federal and state laws and before patients' best interests and well-being.

10. In addition to corrupting the treatment decisions for tens of thousands of Medicare and Medicaid patients, Janssen has been further defrauding the federal and state governments by misrepresenting the "Average Sales Prices" ("ASP") and "Best Prices" for Remicade and Simponi ARIA in quarterly reports submitted to the federal government. Janssen's quarterly ASP and Best Price reports for Remicade and Simponi ARIA are inflated because the Company has not been taking into account the value of all of the free business advisory and practice management services it provides to physician practices in connection with their purchases of Remicade and Simponi ARIA, as federal law requires.

11. Janssen's false ASP reports have caused Medicare and Medicaid to pay inflated reimbursement amounts for Remicade and Simponi ARIA, and have rendered false all claims for reimbursement for Remicade and Simponi ARIA presented to Medicare and the state Medicaid programs that reimburse for these drugs based on the ASP system.

12. Similarly, as a result of its inflated Best Price reports, Janssen has knowingly failed to pay the full rebate due and owing to the state Medicaid programs under the Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8, which correspondingly is causing the federal government to pay substantially more than it should be paying in order to cover its portion of the cost of Remicade and Simponi ARIA under the Medicaid program.

13. Moreover, since at least 2010, Janssen has been fraudulently reporting inflated "Best Prices" by reallocating part of the discount it provides to rheumatology and gastroenterology practices on purchases of Remicade and Simponi ARIA made through Janssen's Contract Purchase Program to subsequent purchase transactions. Through this

fraudulent scheme, Janssen conceals the true Best Prices for Remicade and Simponi ARIA by making them appear slightly higher than the prices that it reports to the government, thereby reducing the amount of the rebates it pays to the state Medicaid programs under the Medicaid Drug Rebate Statute.

II. JURISDICTION & VENUE

14. Jurisdiction is founded upon the Federal FCA, 31 U.S.C. §§ 3729 *et seq.*, specifically 31 U.S.C. §§ 3732(a) & (b) and also 28 U.S.C. §§ 1331 & 1345. The Court may exercise personal jurisdiction over Janssen because it transacts business in this District and is engaging in the alleged illegal activities and practices in this District.

15. Venue in the District of Massachusetts is appropriate under 31 U.S.C. § 3732(a), in that many of the acts complained of took place in this District.

III. PARTIES

16. The United States is a plaintiff to this action. Through the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), the United States administers the Medicare and Medicaid programs.

17. The State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Vermont, the Commonwealth of Virginia, and the State of Washington are plaintiffs to this action. The

Plaintiff States bring this action on behalf of their respective Medicaid programs and agencies as well as their respective State interests.

18. Relator J. Doe worked for Janssen as an Area Business Specialist.

19. Defendant Janssen Biotech, Inc. (f/k/a Centocor Ortho Biotech Inc. and Centocor, Inc.) is a manufacturer and seller of pharmaceutical products. As relevant here, Janssen manufactures and sells the biopharmaceuticals Remicade and Simponi ARIA. Janssen is a Pennsylvania corporation and maintains its headquarters at 800 Ridgeview Road in Horsham, Pennsylvania. Janssen is a wholly-owned subsidiary of Johnson & Johnson ("JNJ").

IV. LEGAL BACKGROUND

A. The Medicare & Medicaid Programs

20. ***Medicare*** is a federal program that provides federally subsidized health insurance for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq*. Part B of the Medicare program provides supplemental benefits to participants to cover, among other things, physician services and prescription drugs. *See generally id.* §§ 1395j–1395w-4. Part D of the Medicare program, which was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, provides prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through CMS, contracts with private companies to administer prescription drug plans. These companies, in turn, enter into subcontracts with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

21. ***Medicaid*** is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payment, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's

per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). The FMAP currently ranges from 50% to 71%, depending on the state.

B. The Federal & State Anti-Kickback Statutes

22. The primary purpose of the Federal AKS, 42 U.S.C. § 1320a-7b(b), is to protect patients and the federal health care programs from the corruptive influence of kickbacks and bribes on treatment decisions. The Medicare and Medicaid programs rely upon physicians to provide treatment that is medically necessary and appropriate. When a drug company, like Janssen, pays kickbacks or bribes to induce a physician to use its products, it taints the physician's decisions and compromises the integrity of the physician-patient relationship.

23. To protect patients and the government health care programs from medically unnecessary treatment, treatment of inferior quality, and harmful treatment, Congress enacted the Federal AKS in 1972, barring the payment of kickbacks and bribes to physicians. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) & (c). Congress subsequently strengthened the statute in 1977 and again in 1987 to ensure that kickbacks disguised as legitimate transactions do not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

24. Violation of the Federal AKS is a felony punishable by fines and imprisonment, and can also result in exclusion from participation in federal health care programs. *See* 42 U.S.C. §§ 1320a-7b(b)(2) & (7).

25. Specifically, the Federal AKS makes it illegal for individuals or entities to "knowingly and willfully offer[] or pay[] remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person

... to purchase, ... order, ... or recommend purchasing ... or ordering any good ... service or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

26. Most of the Plaintiff States have likewise enacted an anti-kickback law that prohibits the payment or acceptance of kickbacks in connection with the purchase or ordering of goods or the provision of any services covered by their Medicaid programs. *See* Cal. Welf. & Inst. Code §§ 14107.2(a) & (b); Conn. Gen. Stat. §§ 53a-161c & 53a-161d; Del. C. tit. 31 § 1005; D.C. Code §§ 4-802(c) & (d); Fla. Stat. § 409.920(2); Haw. Medicaid Provider Manual, ch.2 2.8.2; 305 Ill. Comp. Stat. 5/8A-3; Ind. Code § 12-15-24-2; La. Rev. Stat. § 46:438.2; Md. Code, Crim. Law §§ 8-511 & 8-516; Mass. Gen. Laws ch. 118E, § 41; Mich. Comp. Laws § 400.604; Minn. R. § 9505.2165-4(C); Mont. Code § 45-6-313(1)(b); Nev. Rev. Stat. § 422.560; Nev. Medicaid Services Manual ch. 3303.1A; N.J. Stat. § 30:4d-17(c); NM Stat. §§ 30-41-1 & 30-41-2; N.Y. Code Crim. Proc. § 515.2(b)(5); N.Y. Soc. Serv. Law § 366-d(2); N.C. Gen Stat. §§ 108A-63(g) & (h); Okla. Stat. tit. 56, § 1005(A)(6); R.I. Gen. Laws § 40-8.2-3(a)(2); Tex. Hum. Res. Code § 32.039(b)(1-b) - (1-f); Tex. Penal Code § 35A.02(a)(5); Va. Code § 32.1-315; and Wash. Rev. Code § 74.09.240(1).

27. Free practice management and business advisory services provided by a drug company to physicians to induce them to prescribe and administer the company's products to Medicare and Medicaid beneficiaries constitute illegal remuneration under the Federal AKS and State AKS.

28. To be eligible to participate in the Medicare program and be reimbursed for treatment provided to Medicare beneficiaries, providers are required to enter into a provider agreement in which the provider makes the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application (CMS-855B).

29. Likewise, providers participating in the Medicaid program are required to sign enrollment agreements with the state. Although there are variations in each state's Medicaid provider agreement, all of these agreements require that the provider comply with all state and federal laws, including the State AKS and Federal AKS and Medicaid regulations, in billing the state Medicaid program for drugs and services furnished to Medicaid beneficiaries.

30. On each Form CMS-1500 submitted to Medicare or Medicaid for payment for drugs and services furnished to beneficiaries, a provider certifies, among things, that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute":

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; … 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE ….

31. Accordingly, compliance with the Federal AKS is a material condition of payment for Medicare and Medicaid claims. Similarly, compliance with the Federal AKS and State AKS is a material condition of payment for Medicaid claims. Claims for payment for drugs

and services that are tainted by illegal kickbacks are not authorized to be paid by Medicare and Medicaid and thus constitute claims that are both legally and factually false.

32. In addition to the various laws and regulations all pharmaceutical companies are required to follow, the federal government offers industry guidance in an effort to police the marketing activities of the pharmaceutical industry. For instance, the Office of the Inspector General of the Department of Health and Human Services ("HHS-OIG") issued "Special Fraud Alerts" in 1994 explaining that:

> In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product. …

59 Fed. Reg. at 65,376 (Dec. 19, 1994). HHS-OIG has also specifically warned that free training for a physician's office staff in areas such as management techniques and CPT coding are suspect incentive arrangements that violate the Federal AKS if one of the purposes of the incentive is to influence a physician's medical decision regarding the treatment ordered for a Medicare or Medicaid patient. *See id.* As the government has observed:

> A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the Federal government's costs of reimbursing suppliers for the products. …

Id.

33. Thereafter, in April 2002, HHS-OIG issued its Compliance Program Guidance for Pharmaceutical Manufacturers, a document meant to provide an overview of the fundamental elements of a pharmaceutical manufacturer compliance plan, which identifies and discusses specific risk areas. HHS-OIG advised that "[a]nytime a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product the manufacturer should examine whether it is providing a tangible benefit to the physician with the intent to induce or reward referrals." HHS-OIG Guidance to Pharmaceutical Manufacturers (Apr. 2002) at 28.

34. HHS has also published safe harbor regulations that define practices that are not subject to prosecution or sanctions under the Federal AKS because such practices are unlikely to result in fraud or abuse. *See* 42 C.F.R. §1001.952. However, only those arrangements that precisely meet all of the conditions set forth in a safe harbor are afforded safe harbor protection. None of the practices at issue here meet these safe harbor regulations.

35. Moreover, to provide guidance on the Federal AKS, HHS-OIG also offers interested parties the opportunity to seek "formal advisory opinions" regarding the application of the Federal AKS and its safe harbor regulations to any existing or proposed business arrangement. *See* 42 C.F.R. Part 1008.

C. The Federal & State False Claims Acts

36. On May 20, 2009, Congress enacted the Fraud Enforcement Recovery Act (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the Federal FCA and re-designated § 3729(a)(1) as § 3729(a)(1)(A), § 3729(a)(2) as § 3729(a)(1)(B), § 3729(a)(7) as § 3729(a)(1)(G), and § 3729(b) as §§ 3729(b)(1)(A) & (B).

37. The pre-FERA version of the Federal FCA imposed liability on:

> [A]ny person who—
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]
>
> * * *
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

31 U.S.C. §§ 3729(a)(1), (2) & (7). The Federal FCA, as FERA has amended it, now imposes liability on:

> [A]ny person who—
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> * * *
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government[.]

31 U.S.C. §§ 3729(a)(1)(A), (B) & (G).

38. The term "knowingly" means "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b) (pre-FERA); 31 U.S.C. § 3729(b)(1)(A) (post-FERA). Proof of specific intent to

defraud is not required. *See* 31 U.S.C. § 3729(b) (pre-FERA); 31 U.S.C. § 3729(b)(1)(B) (post-FERA).

39. FERA provides that amendments to the Federal FCA became effective upon enactment except for the amendment to § 3729(a)(2), which "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act ... that are pending on or after that date." FERA § 4(f)(1), 123 Stat. at 1625.

40. Here, Janssen's alleged Federal FCA violations began prior to 2006 and are still occurring. Accordingly, the pre-FERA §§ 3729(a)(1), 3729(a)(7), and 3729(b) apply to all alleged Federal FCA violations that occurred before May 20, 2009 and the amended versions of those Sections (§ 3729(a)(1)(A), § 3729(a)(1)(G) and §§ 3729(b)(1)(A) & (B)) apply to all alleged Federal FCA violations that occurred on or after May 20, 2009. In addition, pre-FERA § 3729(a)(2) applies to all claims no longer pending as of June 7, 2008, and the amended version (§ 3729(a)(1)(B)) applies to all alleged false claims pending on or after June 7, 2008.

41. Section 3729(a)(1) of the Federal FCA provides that a person is liable to the United States Government for three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of $5,000 to $10,000 per violation. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), 64 Fed. Reg. 47099, 47103 (1999), and 28 C.F.R. § 85.3 (2015), the Federal FCA civil penalties were adjusted to $5,500 to $11,000 per violation for violations occurring on or after October 23, 1996. In accordance with the Federal Civil Penalties Inflation Adjustment Act of 2015, the Federal FCA civil penalty amounts were again adjusted, this time to $10,781 to $21,563 per violation for violations

occurring after November 2, 2015. *See* 28 C.F.R. §§ 85.3 & 85.5 (2016); 81 Fed. Reg. 42491, 42500 (2016).

42. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f)(1), 124 Stat. 759, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the Federal FCA]." As stated in the legislative history of the PPACA, the purpose of this amendment was to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the [Federal FCA], even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

43. Each of the Plaintiff States has enacted a false claims statute modeled after the Federal FCA. *See* California False Claims Act (Cal. Gov't. Code §§ 12650 *et seq*.), Colorado Medicaid False Claims Act (Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq*.), Connecticut False Claims Act (Conn. Gen. Stat. §§ 17b-301b *et seq*.), Delaware False Claims and Reporting Act (Del. Code tit. 6, §§ 1201 *et seq*.), District of Columbia False Claims Act (D.C. Code §§ 2-308.13 *et seq.*), Florida False Claims Act (Fla. Stat. §§ 68.081 *et seq.*), the Georgia State False Medicaid Claims Act (Ga. Code §§ 49-4-168 *et seq.*), Hawaii False Claims Act (Haw. Rev. Stat. §§ 661-21 *et seq.*), Illinois False Claims Act (740 Ill. Comp. Stat. 175/1 *et seq.*), Indiana False Claims and Whistleblower Protection Act (Ind. Code §§ 5-11-5.5-1 *et seq.*), Iowa False Claims Act (Iowa Code §§ 685.1 *et seq.*), Louisiana Medical Assistance Programs Integrity Law (La. Rev. Stat. §§ 46:438.1 *et seq*.), Maryland False Health Claims Act (Md. Code, Health-General §§ 2-601 *et seq*.), Massachusetts False Claims Law (Mass. Laws. ch. 12, §§ 5A *et seq*.), Michigan Medicaid False Claims Act (Mich. Comp. Laws §§ 400.601 *et seq*.), Minnesota False Claims Act (Minn.

Stat. §§ 15C.01 *et seq*.), Montana False Claims Act (Mont. Code §§ 17-8-401 *et seq*.), Nevada False Claims Act (Nev. Rev. Stat. §§ 357.010 *et seq*.), New Jersey False Claims Act (N.J. Stat. §§ 2A:32C-1 *et seq*.), New Mexico Medicaid False Claims Act (N.M. Stat. § 27-14-1 *et seq*.), New York False Claims Act (N.Y. State Fin. Law §§ 187 *et seq*.), North Carolina False Claims Act (N.C. Gen. Stat. §§ 1-605 *et seq*.), Oklahoma Medicaid False Claims Act (Okla. Stat. tit. 63, §§ 5053 *et seq*.), Rhode Island False Claims Act (R.I. Gen. Laws §§ 9-1.1-1 *et seq*.), Tennessee Medicaid False Claims Act (Tenn. Code §§ 71-5-181 *et seq*.), Texas Medicaid Fraud Prevention Act (Tex. Hum. Res. Code §§ 36.001 *et seq*.), Vermont False Claims Act (32 Vt. Stat. §§ 630 *et seq*.), Virginia Fraud Against Taxpayers Act (Va. Code §§ 8.01-216.1 *et seq*.), and Washington Medicaid Fraud False Claims Act (Wash. Rev. Code §§ 74.66 *et seq*.).

44. Claims that arise from a kickback scheme violate the Federal FCA and State FCAs for two separate and distinct reasons:

- Claims that result from a kickback scheme are per se false because the Federal AKS and State AKS prohibit the government from paying for services or drugs tainted by kickbacks. Accordingly, claims seeking payment for services or prescriptions tainted by kickbacks are both legally and factually false.

- To participate in federally-funded and state-funded health care programs, providers must certify in their provider enrollment agreement that they will comply with the Federal AKS and State AKS.

- In submitting claims for payment to Medicare and Medicaid for services or drugs tainted by kickbacks, providers certify that they have complied with the Federal AKS and State AKS in providing such services or drugs.

45. Consequently, if a party pays a kickback to induce the prescription of a particular drug, it renders false the submitter's implied or express certification of compliance that the resulting claim complies with the requirements of the Federal AKS and State AKS.

V. FACTUAL ALLEGATIONS

A. Janssen's Biologic Drugs - Remicade & Simponi ARIA

1. *Remicade*

46. Remicade is the brand name for infliximab, which is in a class of medications called biologic response modifiers. More particularly, Remicade is a tumor necrosis factor-alpha ("TNF-alpha") inhibitor, as it targets TNF-alpha, which is a substance in the body that causes inflammation. The FDA has approved Remicade for the following indications among others:

- Treatment of patients with ***moderately to severely active rheumatoid arthritis*** (administered in combination with methotrexate);
- Treatment of patients (adults and children) with ***moderately to severely active Crohn's disease*** who have had an inadequate response to conventional therapy;
- Treatment of patients (adults and children) with ***moderately to severely active ulcerative colitis*** who have had an inadequate response to conventional therapy;
- Treatment of patients with ***psoriatic arthritis***; and
- Treatment of patients with ***active ankylosing spondylitis***.

47. Remicade is administered intravenously (into a vein), a delivery process called infusion. Drug infusions are performed at doctors' offices, hospital outpatient departments, businesses that strictly administer drug infusions, and at home by mobile service providers. The chart below sets forth Remicade's approved dosage and administration by indication.

	Dosage	**Frequency of Administration**
Rheumatoid arthritis	3-10 mg/kg	At least a 2-hour infusion every 4-8 weeks after 3 starter doses
Crohn's disease	5 or 10 mg/kg	At least a 2-hour infusion every 8 weeks after 3 starter doses
Ulcerative colitis	5 mg/kg	At least a 2-hour infusion every 8 weeks after 3 starter doses
Psoriatic arthritis	5 mg/kg	At least a 2-hour infusion every 8 weeks after 3 starter doses
Ankylosing spondylitis	5 mg/kg	At least a 2-hour infusion every 6 weeks after 3 starter doses

48. The FDA requires that Janssen include the following black box warning on Remicade's label:

WARNING: SERIOUS INFECTIONS and MALIGNANCY
See full prescribing information for complete boxed warning.

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.

* * *

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including REMICADE.

- Postmarketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF blockers including REMICADE. Almost all had received azathioprine or 6-mercaptopurine concomitantly with a TNF-blocker at or prior to diagnosis. The majority of REMICADE cases were reported in patients with Crohn's disease or ulcerative colitis, most of whom were adolescent or young adult males.

49. JNJ combined with its subsidiaries, including Janssen, is one of the largest drug companies in the world in terms of sales. Among all of JNJ's drugs, Remicade is number one in terms of sales, making it JNJ's flagship drug. In fact, according to JNJ's 2015 annual report filed with the U.S. Securities and Exchange Commission, Remicade is the top revenue generator of all JNJ products, with sales of the drug accounting for approximately 9.4% of JNJ's total annual revenue. For fiscal year 2015, Janssen reported $4.45 billion in sales of Remicade in the U.S., an increase of nearly 76% since fiscal year 2007.

Remicade U.S. Revenue (Billions)								
2007	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
$2.53	$2.81	$3.08	$3.09	$3.27	$3.58	$3.89	$4.15	$4.45

50. Remicade is among the biggest expenses for the Medicare program. In 2014, Remicade was ranked in the top five in terms of Medicare Part B drug expenditures. In that year alone Medicare paid $1,172,607,402 for Remicade provided to 59,748 beneficiaries (an average of $19,626 for each beneficiary). *See* Medicare Drug Spending Dashboard 2014 (available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-

Reports/Dashboard/Medicare-Drug-Spending/Drug_Spending_Dashboard.html). On average, Medicare beneficiaries paid $3,969 in co-payments for Remicade in 2014.

51. Remicade's patent is set to expire in September 2018. And on February 9, 2016, the FDA's Arthritis Advisory Committee recommended that the first investigational bio-similar version of infliximab be approved for all eligible indications. Pfizer is preparing to launch a bio-similar version of Remicade in the fall of 2016.

2. *Simponi ARIA*

52. Simponi ARIA is the trade name for golimumab, which like Remicade is a TNF-alpha inhibitor.[1]

53. The FDA approved Simponi ARIA in July 2013 for the treatment of adult patients with ***moderately to severely active rheumatoid arthritis*** in combination with methotrexate. Simponi ARIA is not approved for any other uses. Like Remicade, Simponi ARIA is delivered through an infusion. Simponi ARIA's normal dosage is 2 mg/kg, and it is administered for 30 minutes every eight weeks after two starter doses.

54. The FDA requires that Janssen include the following black box warning on Simponi ARIA's label:

[1] Simponi (as opposed to Simponi ARIA) is a formulation of golimumab that is administered through subcutaneous injection and is also available in an auto-injector. Simponi was approved in 2009 for the treatment of adult patients with ***moderately to severely active rheumatoid arthritis*** (to be administered in combination with methotrexate) and ***active ankylosing spondylitis***. Simponi is also approved for patients with ***active psoriatic arthritis*** and ***moderately to severely active ulcerative colitis*** who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or mercaptopurine. Janssen has different sales representatives promote Simponi and Simponi ARIA.

WARNING: SERIOUS INFECTIONS AND MALIGNANCY
See full prescribing information for complete boxed warning.

- Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal (such as histoplasmosis), and other opportunistic infections have occurred in patients receiving SIMPONI ARIA

* * *

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which SIMPONI ARIA is a member.

55. Because Janssen is scheduled to lose its exclusivity rights to infliximab in September 2018, to get rheumatologists accustomed to using Simponi ARIA before other drug companies begin selling bio-similar infliximab, Janssen has been advising its top rheumatology accounts to prescribe Simponi ARIA instead of Remicade for rheumatoid arthritis patients.

56. Sales of Simponi ARIA and Simponi in the United States have grown by over 80% between 2013 and 2015.[2]

2013	2014	2015
$404 million	$544 million	$730 million

3. *The Contract Purchase Program*

57. Since no later than 2007, Janssen has offered the "Contract Purchase Program" ("CPP") through which certain physician practices can qualify for discounted pricing on their purchases of Remicade. All physician practices that enter into the CPP receive a discounted price on Remicade purchases. The practices, however, can earn a greater discount if they increase the amount of Remicade they purchase. Each quarter Janssen measures these customers' purchase volume. If they purchase more vials of Remicade in a quarter compared to the same quarter in the prior year, they earn the additional discount. And since Janssen sets multiple growth tiers, the

[2] In its publicly disclosed financial reports, JNJ combines sales of Simponi ARIA and Simponi.

amount of the additional discount per vial increases when a physician practice's purchase growth surpasses the minimum growth percentage assigned to each performance tier.[3]

58. Janssen added Simponi ARIA to the CPP in 2013 and began basing the amount of the additional discounts it offers to physician practices on the combined growth of Remicade and Simponi ARIA.

59. Below is a chart from a Janssen brochure that provides an overview of the CPP's discount tiers:

Tier	Total Vials % Change (Current Year Quarter vs Prior Year Quarter)	Price Per Vial	Additional Discount Per Vial	
	Less than or equal to 0%	CPP Price	SIMPONI ARIA®	REMICADE®
	CPP Performance-Based Discounts			
1	Greater than 0% and less than 5%	CPP Price and Discount	$7.50	$2.50
2	Greater than or equal to 5%	CPP Price and Discount	$25.00	$5.00

60. Importantly, Janssen only offers the CPP to single health care provider entities that own, manage or control a physician, group of physicians, physician practice, or physician clinic. Janssen does not offer the CPP to hospitals, hospital-owned practices, or physicians employed by hospitals.

61. In addition, to participate in the CPP program a physician practice must agree to keep the terms of the CPP agreement as well as the pricing and discounts available under the

[3] Janssen created and makes available to providers a tool called the "Program Overview & Contractor Estimator" so physician practices can see how many more Remicade or Simponi ARIA infusions they must administer to reach the next discount tier.

CPP confidential. The physician practices may disclose the information if required by law, but must provide Janssen with reasonable notice prior to doing so.

B. Rheumatoid Arthritis, Crohn's Disease, Ulcerative Colitis, Psoriatic Arthritis, and Ankylosing Spondylitis and the Various Biologic Drugs Approved to Treat These Diseases

1. *Rheumatoid arthritis*

62. Rheumatoid arthritis is an inflammatory disease that causes pain, swelling, stiffness, and loss of function in the joints. This disease occurs when the immune system, which normally defends the body from invading organisms, attacks the membrane lining the joints. Although the disease often begins in middle age and occurs with increased frequency in older people, older teenagers and young adults may also be diagnosed with the disease.

63. Rheumatoid arthritis affects people differently. In most cases it is chronic. Some people have mild or moderate forms of the disease, with periods of worsening symptoms, called flares, and periods in which they feel better, called remissions. Other people have a severe form of the disease that is active most of the time, lasts for many years or a lifetime, and leads to serious joint damage and disability.

64. Most people who have rheumatoid arthritis seek treatment from physicians who specialize in rheumatology. Rheumatologists often prescribe medications to reduce patients' pain and slow the course of the disease. Depending on the severity of a patient's rheumatoid arthritis symptoms, physicians may prescribe:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) – ibuprofen, naproxen, Celebrex (Celecoxib), Mobic (meloxicam), Indocin (indomethacin), Voltaren (diclofenac), and Arthrotec (diclofenac and misoprostol);
- Disease-modifying anti-rheumatic drugs (DMARDs) – methotrexate, hydroxychloroquine, leflunomide, sulfasalazine, apremilast, tofacitinib; or

- Biologics[4]:

  TNF-alpha biologics – Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), **Remicade (infliximab)**, Simponi (golimumab), and **Simponi ARIA (golimumab)**; or

  Non-TNF biologics – Actemra (tocilizumab), Orencia (abatacept), Rituxan (rituximab), and Xeljanz (tofacitinib).

65. Typically, biologics are only used when NSAIDs and DMARDs are inadequate in reducing the symptoms of rheumatoid arthritis. Depending on the specific drug, biologics may be used alone or in combination with the DMARD methotrexate. Due to the risk of serious infection, the biologics are not used in combination with each other.

66. The American College of Rheumatology ("ACR") recommends that patients with early or established rheumatoid arthritis[5] start with NSAIDs or DMARD monotherapy, preferably methotrexate. If after DMARD monotherapy the disease activity progresses to a moderate or high severity, the ACR recommends that the patient use (in no order of preference) combination DMARDs, a TNF-alpha biologic, or a non-TNF biologic. *See* 2015 Am. College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.

67. NSAIDs and DMARDs are taken orally or by subcutaneous injection. Remicade and Simponi ARIA are administered through infusion. Other biologics are administered by subcutaneous injection or by tablet. The table below provides the method of delivery for commonly prescribed biologics approved for rheumatoid arthritis:

[4] Biopharmaceuticals, unlike chemical medications, are made out of material found in life, usually proteins. Many biologic treatments are proteins called antibodies, which normally are part of the body's immune defense. The antibodies used for biologic therapy have been developed to bind and interfere with the inflammatory process in a disease.

[5] A patient who has had rheumatoid arthritis for less than six months is deemed to have "early" rheumatoid arthritis, and a patient who has had rheumatoid arthritis for more than six months is considered to have "established" rheumatoid arthritis.

	Method of Administration
TNF-alpha biologics:	
Cimzia (certolizumab pegol)	Subcutaneous Injection or Infusion
Enbrel (etanercept)	Subcutaneous Injection
Humira (adalimumab)	Subcutaneous Injection
Remicade (infliximab)	Infusion
Simponi (golimumab)	Subcutaneous Injection
Simponi ARIA (golimumab)	Infusion
Non-TNF biologics:	
Actemra (tocilizumab)	Subcutaneous Injection or Infusion
Orencia (abatacept)	Subcutaneous Injection or Infusion
Rituxan (rituximab)	Infusion
Xeljanz (tofacitinib)	Tablet

68. Janssen has not conducted head-to-head clinical trials to determine whether Remicade and/or Simponi ARIA are more efficacious in treating rheumatoid arthritis than other TNF biologics or the non-TNF biologics.

69. Accordingly, there are multiple drug options for relieving the symptoms and slowing the progression of rheumatoid arthritis.

70. Notably, rheumatoid arthritis drugs have the second highest total sales of all drugs worldwide with over $40 billion sales. The rheumatoid arthritis drugs with the highest market share in the United States are Humira, Enbrel, and Remicade. *See* Eric Palmer, *Top 10 Rheumatoid Arthritis Drugs 2013*, FiercePharma (Sep. 16, 2013) (available at http://www.fiercepharma.com/sales-and-marketing/top-10-rheumatoid-arthritis-drugs-2013 (last viewed on Oct. 12, 2016)).

2. *Crohn's disease & ulcerative colitis*

71. *Crohn's disease* is a chronic disease that causes inflammation in the gastrointestinal tract. The disease most often begins gradually and can become worse over time. Most people have periods of remission that can last for weeks or years. Complications of

Crohn's disease can include bowel obstruction, fistulas, anal fissures, ulcers, malnutrition, and inflammation in the joints, eyes, and skin.

72. *Ulcerative colitis* is a chronic disease that causes inflammation and ulcers on the inner lining of the large intestine. Ulcerative colitis most often begins gradually and can become worse over time. Symptoms can be mild to severe. Most people have periods of remission that can last for weeks or years.

73. There is no cure for Crohn's disease or ulcerative colitis, but medicine can reduce the symptoms of the diseases. Most people who have Crohn's disease or ulcerative colitis seek treatment from physicians who specialize in gastroenterology. Gastroenterologists often prescribe medications to slow the course of the disease, keep patients in remission, and reduce patients' pain.

74. Conventional or first line treatment for Crohn's disease and ulcerative colitis typically involves the use of aminosalicylates (sulfasalazine, mesalamine, olsalazine, and balsalazide), corticosteroids (prednisone, methylprednisolone and budesonide), and/or immunomodulators (methotrexate, 6-mercaptopurine (6-MP), azathioprine, and cyclosporine). When conventional treatment fails gastroenterologists usually step up the patients' treatment to one of the following biologic drugs:

- TNF-alpha biologics – Cimzia (certolizumab pegol), Humira (adalimumab), **Remicade (infliximab)**, and Simponi (golimumab); or
- Non-TNF biologic – Entyvio (vedolizumab) and Tysabri (natalizumab).

75. Depending on the specific biologic, it may be used alone or in combination with a first line medicine. However, due to the risk of serious infection, the biologic drugs are not used in combination with each other.

76. Some biologics, such as Cimzia, Humira, and Simponi, are administered by subcutaneous injection while Entyvio and Remicade are administered through infusion. The table below provides the method of delivery for commonly prescribed biologics approved for Crohn's disease and ulcerative colitis.

	Method of Administration
TNF-alpha biologics:	
Cimzia (certolizumab pegol) – Crohn's disease only	Subcutaneous Injection
Humira (adalimumab)	Subcutaneous Injection
Remicade (infliximab)	Infusion
Simponi (golimumab) – ulcerative colitis only	Subcutaneous Injection
Non-TNF biologics:	
Entyvio (vedolizumab)	Infusion
Tysabri (natalizumab)	Infusion

77. Janssen has not conducted head-to-head clinical trials to determine whether Remicade is more efficacious in treating Crohn's disease or ulcerative colitis than other TNF biologics or the non-TNF biologics.

78. Accordingly, for patients who have an inadequate response to first line therapy, there are multiple biologic drug options for relieving the symptoms of Crohn's disease and ulcerative colitis.

3. *Psoriatic arthritis*

79. Psoriatic arthritis is an inflammatory arthritis that usually arises with skin psoriasis. It causes joint pain and swelling that can lead to damage of the joint if the inflammation is not controlled.

80. The disease is treatable but not curable. Most people who have psoriatic arthritis seek treatment from a rheumatologist. Rheumatologists often prescribe medications to reduce patients' pain and slow the course of the disease. Depending on the severity of a patient's symptoms, rheumatologists will prescribe, individually or in combination, corticosteroids,

nonsteroidal anti-inflammatory drugs (NSAIDs), disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate and sulfasalazine, and/or biologics, including Humira (adalimumab), Cimzia (certolizumab pegol), Enbrel (etanercept), **Remicade (infliximab)**, Stelara (ustekinumab), and Cosentyx (secukinumab). Due to the risk of serious infection, the biologic drugs are not used in combination with each other.

81. Some biologics approved for treatment of psoriatic arthritis, such as Cimzia, Cosentyx, Enbrel, Humira, Simponi, and Stelara, are administered by subcutaneous injection while Entyvio and Remicade are administered through infusion. The table below provides the method of delivery for commonly prescribed biologics approved for psoriatic arthritis.

	Method of Administration
TNF-alpha biologics:	
Cimzia (certolizumab pegol)	Subcutaneous Injection
Humira (adalimumab)	Subcutaneous Injection
Remicade (infliximab)	Infusion
Simponi (golimumab)	Subcutaneous Injection
Non-TNF biologics:	
Cosentyx (secukinumab)	Subcutaneous injection
Entyvio (vedolizumab)	Infusion
Stelara (ustekinumab)	Subcutaneous Injection

82. Janssen has not conducted head-to-head clinical trials to determine whether Remicade is more efficacious in treating psoriatic arthritis than other biologics.

83. Accordingly, there are multiple drug options for relieving the symptoms and slowing the progression of psoriatic arthritis.

4. ***Ankylosing spondylitis***

84. Ankylosing spondylitis is a form of progressive arthritis that causes chronic inflammation of the joints in the spine. Many people with ankylosing spondylitis have mild episodes of back pain that come and go. Other people who have this disease suffer severe, ongoing pain accompanied by loss of flexibility of the spine. In some people, ankylosing

spondylitis can affect joints outside of the spine, like the shoulders, ribs, hips, knees, and feet, and organs, such as the eyes, bowel, and more rarely the heart and lungs.

85. There is no cure for ankylosing spondylitis, but some treatments relieve symptoms of the disorder and may possibly prevent its progression. Most people who have ankylosing spondylitis seek treatment from a rheumatologist. Rheumatologists often prescribe medications to reduce patients' pain and slow the course of the disease.

86. Depending on the severity of the symptoms, first line treatment for ankylosing spondylitis typically involves the use of NSAIDs (ibuprofen, naproxen, Celebrex (Celecoxib), Mobic (meloxicam), Indocin (indomethacin), Voltaren (diclofenac), and Arthrotec (diclofenac and misoprostol)), and/or DMARDs (methotrexate and sulfasalazine). If the first line therapy fails, treatment frequently steps up to a TNF-alpha biologic (Humira (adalimumab), Cimzia (certolizumab pegol), Enbrel (etanercept), **Remicade (infliximab)**), or Simponi (golimumab). Due to the risk of serious infection, the biologic drugs are not used in combination with each other.

87. NSAIDs and DMARDs are taken orally or by subcutaneous injection. With regard to the biologics, Cimzia, Enbrel, Humira, and Simponi are administered by subcutaneous injection, and Remicade is administered through infusion.

88. Janssen has not conducted head-to-head clinical trials to determine whether Remicade is more efficacious in treating psoriatic arthritis than other TNF biologics.

89. Accordingly, there are multiple drug options for relieving the symptoms and slowing the progression of ankylosing spondylitis.

C. How Rheumatology and Gastroenterology Practices Are Reimbursed for Biologic Drugs and Infusion Services

1. *Reimbursement for infusible biologics Remicade and Simponi ARIA*

90. There are two ways for rheumatology and gastroenterology practices that have infusion suites to purchase infusible biologics such as Remicade and Simponi ARIA:

- Buy-and-bill – the practice purchases the drug from a distributor, maintains an inventory of the drug, and after administration to the patient bills the health plan for the service of administering the infusion and for the drug itself; or
- Specialty pharmacy – the practice orders the drug from a specialty pharmacy and after administering it to the patient bills the health plan for the service of administering the infusion; the specialty pharmacy bills the health plan for the drug.

91. Most rheumatology and gastroenterology physician practices that operate an in-office infusion suite use the buy-and-bill method because it offers them an opportunity to earn a profit (also referred to as a spread) on each vial of Remicade and Simponi ARIA because their acquisition cost on the drugs is lower than the reimbursement amount.

92. After physician practices infuse Remicade and Simponi ARIA to patients, they submit claims for reimbursement on Form CMS-1500 on behalf of those patients to their insurers, including Medicare, Medicaid, and private payers.

93. ***Medicare Part B*:** Part B of the Medicare program reimburses physicians for drugs, including Remicade and Simponi ARIA, based on the drugs' Average Sales Price ("ASP") plus 6% of the ASP. After the beneficiary's deductible is met, Medicare pays 80% of the set rate (ASP + 6%), and the patient or secondary insurance is responsible for the remaining 20%. The vast majority of Medicare patients have supplemental coverage (*e.g.*, a Medigap plan or Medicaid) that pays the 20% coinsurance. If a Medicare patient does not have a supplemental policy, there are foundations that may assist with the 20% co-pay.

94. Significantly, Medicare does not require a prior authorization or that a patient first try a biologic administered through subcutaneous injection before it will cover Remicade or Simponi ARIA.

95. ***Medicaid*:** Although each Plaintiff State administers its own Medicaid program and payment policies vary by state, most states pay physicians ASP plus 6% for infusible biologics that they purchase and administer.[6]

96. ***Commercial Payers*:** The reimbursement rate that commercial payers pay physician practices is typically based on an ASP-based formula.[7] The reimbursement rates that commercial payers pay are often higher than the Medicare and Medicaid reimbursement rates (ASP + 6%). In addition, as described in paragraph 137(e) below, providers, with Janssen's assistance, are frequently able to negotiate higher reimbursement rates from commercial payers.

97. Over the last several years, the increasing trend is for commercial payers to require that patients fail one, two, or three subcutaneous injectable biologics before they will cover an infusible biologic such as Remicade or Simponi ARIA. This is referred to as "step therapy" because the insurers require that the patients try and fail other less expensive medications before "stepping up" to costlier drugs. With regard to Remicade and Simponi ARIA, many insurers require step therapy because the biologics delivered by subcutaneous injection are equally effective but far less expensive since they do not involve the infusion service.

[6] Certain state Medicaid programs require drug acquisition through a specialty pharmacy, in which case the provider may only bill for the administration service.

[7] Certain commercial payers may require drug acquisition through a specialty pharmacy, in which case the provider may only bill for the administration service.

2. *Reimbursement for infusion services*

98. ***Medicare Part B*:** Medicare Part B reimburses physicians for administering the infusion by paying a service fee set forth in the outpatient Physician Fee Schedule ("PFS").

99. For the two-hour Remicade infusions, the physician practices bill the first hour under CPT code 96413 and the second hour under CPT code 96415. For the 30-minute Simponi ARIA infusions, the physician practices bill under CPT code 96413. For example, in 2013 Medicare paid physicians in Massachusetts (everywhere but metropolitan Boston) approximately $151 for the first hour of an infusion and $32 for each subsequent hour. *See* 2013 Medicare Physician Fee Schedule.

100. After the patient's deductible is met, Medicare pays 80% of the set rate, and the patient or secondary insurance is responsible for the remaining 20%.

101. ***Medicaid*:** Although each Plaintiff State administers its own Medicaid program and payment policies vary by state, states frequently use a fee schedule to reimburse physicians for office based infusion services under Medicare's PFS. Several states require prior authorization.

102. ***Commercial Payers*:** Most commercial payers reimburse for infusion services based on Medicare's PFS rates plus a negotiated premium. Commercial payers typically pay a higher reimbursement fee for infusion services than Medicare and Medicaid.

3. *Reimbursement for self-injectable biologics*

103. For purposes of this Complaint, a biologic drug that is approved for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, and/or psoriatic arthritis and that is delivered by subcutaneous injection, including, but not limited to,

Actemra, Cimzia, Enbrel, Humira, Orencia, and Simponi, is referred to herein as a "Self-Injectable," and these drugs are collectively referred to as the "Self-Injectables."

104. Medicare Part B will cover 80% of the cost of a Self-Injectable and the injection procedure (CPT Code 96401) when the Self-Injectable is administered in the physician's office incident to a service.

105. When purchased from a pharmacy and self-administered at home the Self-Injectables are covered under Medicare Part D. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses a Self-Injectable to that Part D beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor and receives reimbursement for the portion of the Self-Injectable's cost not paid by the beneficiary.

106. In view of the infusion service revenue as well as the profit earned on each vial of Remicade and Simponi ARIA purchased, physician practices earn a higher profit by prescribing and administering Remicade and Simponi ARIA than merely prescribing a Self-Injectable or biologic that is taken orally.

D. Janssen Helps Rheumatology and Gastroenterology Practices Establish Infusion Businesses and Provides Free Practice Management Services to Induce Them to Prescribe and Infuse Remicade and Simponi ARIA

107. The largest and most important market for Remicade and Simponi ARIA sales is rheumatology and gastroenterology practices that have an in-office infusion suite. Since at least 2003, Janssen has been using the illegal kickback scheme detailed below to expand the in-office infusion market and grow sales of Remicade and Simponi ARIA in this market.

108. Janssen has determined that in-office infusion suites that follow its practice management guidance can generate revenue of approximately $1,400 to 2,000 per infusion chair

each day from the spread on the drugs and infusion service reimbursements. And since the typical in-office infusion suite has four or five chairs, the total daily revenue that a private practice earns from an in-office infusion suite is $7,000 to $10,000. Moreover, Janssen has determined that at an efficiently operated in-office infusion suite one nurse can manage five infusion chairs at the same time. The average daily cost of a nurse is $320 ($40 per hour for an eight-hour day). Consequently, a practice with an in-office infusion suite that has five chairs can net $6,650 to $9,650 per day in profits.

109. One of Janssen's principal strategies for expanding the in-office infusion market and growing sales of Remicade and Simponi ARIA is to advise rheumatology and gastroenterology practices about how these drugs offer a lucrative business opportunity that Self-Injectables or other biologics taken orally do not offer – a significant payment for each Remicade and Simponi ARIA infusion in addition to a profit on every vial of the drugs purchased. Janssen emphasizes to rheumatology and gastroenterology practices that this revenue stream is "passive income" that can be generated without placing additional time burdens on the physicians and with very little up-front investment, as the only start-up costs are the cost of a nurse, the acquisition of Remicade and/or Simponi ARIA, an IV pole, and an infusion chair.

110. Janssen also assures the rheumatology and gastroenterology practices that it will help them establish and set up the infusion suites and also help them effectively operate these infusion businesses. In other words, Janssen effectively becomes a business partner to the physician practices.

111. Janssen employs a large team of highly-trained medical practice advisers to serve as the dedicated business partner to Remicade's and Simponi ARIA's top customers, helping them maximize profits on their in-office infusion suites. Janssen calls these employees "Area

Business Specialists" or "ABSs," and tells practices that they come as part of the in-office infusion suites that Janssen helps establish.

1. *Janssen's team of Area Business Specialists*

112. There are currently over 40 Janssen ABSs nationwide – typically one in each Remicade/Simponi ARIA account territory. Prior to re-districting and reducing the number of ABS territories in or around 2014, Janssen had approximately 70 ABS territories across the country. Because ABSs work primarily with owners and managers of rheumatology and gastroenterology practices and hospital executives to enhance and grow their infusion businesses, Janssen usually hires former practice managers, hospital administrators, and individuals with prior managed care employment experience for ABS positions.

113. Janssen trains ABSs to focus on advising health care providers regarding the establishment and operation of infusion suites and not to initiate discussion concerning the clinical aspects of Remicade and Simponi ARIA. Janssen employs a separate team of sales representatives, referred to as "Immunology Specialists," as well as medical science liaisons ("MSLs") to promote Remicade and Simponi ARIA by providing clinical information and building relationships with rheumatologists and gastroenterologists. However, since some clinical discussion is unavoidable when certain practice management advice is provided, ABSs occasionally must discuss the clinical aspects of Remicade and Simponi ARIA. If an account asks an ABS a clinical question, Janssen trains the ABS to answer the question and then tell the account that the ABS will have the Immunology Specialist or MSL follow-up.

114. To incentivize ABSs to grow sales of Remicade and Simponi ARIA by the accounts in their respective territory, Janssen has tied a significant portion of ABSs' compensation to sales growth at the accounts to which the ABSs provide business advisory

services and the number of new infusion suites that the ABSs help open. Tellingly, although Janssen measures account growth by the increase in the amount of Remicade and Simponi ARIA vials purchased, in internal reports used to track ABSs' performance Janssen makes it appear that account growth is measured by new infusion patients at the accounts irrespective of the brand of biologic infused.

115. In a 2002 internal document, Janssen's predecessor Centocor summarized the ABS position as follows:

> Responsible for securing and preserving patient access to Remicade in the optimal site of care, ideally the physician's office. Within a defined geographic territory, provides **proactive, total account management to targeted accounts with a focus on site of care specific infusion issues, practice management and selling at an executive level.** Additionally, will serve as a resource to territory's accounts and Centocor staff regarding payer policies; reimbursement regulations and processes; practice management; and staffing resources.

(Emphasis added). In that same document, Centocor stated that the ABS position has the following "essential functions," among others:

- "Execute new IOI [in-office infusion] pull-through."
- "Assist members of sales force in all aspects of Remicade promotion, including but not limited to Remicade access and pull-through, shifting SOC [site of care] from HOPD [hospital outpatient department] to IOI [in-office infusion] and reimbursement."
- "Serve as a resource to territory's accounts and Centocor staff re: local, regional and national payer policies; reimbursement regulations and processes (i.e., eligibility and benefit verification, pre-authorization, billing, coding, claims, and appeals/grievances); practice management; Medicare and Medicaid rules and regulations; OSHA; HIPAA; Stark; state-specific clinical staff licensing requirements for Remicade compounding, admixture, administration and monitoring; and staffing resources."
- "Establish alternate sites of care partnerships and leverage for increase patient access."
- "Mentor doctors and staff on how to develop and implement an In Office Infusion program including overall operations management, scheduling,

staffing, pre-authorization, reimbursement, capacity management, inventory management, and infusion management."

- "Train appropriate clinical staff re: technical aspects of infusing Remicade including reconstitution, admixture, administration, monitoring, and adverse event management and reporting."

- "Act as a liaison between providers and Corporate/Government Accounts."

- "Demonstrate appropriate use of resources, internal and external, to assist accounts and territory (*e.g.*, Hotline, Medical Affairs, MARS)."

116. In a 2015 job posting for an ABS position in Missouri, Janssen described the ABS's role as follows:

> The ABS is accountable to ensure appropriate identified new and existing patients have access to pharmaceutical products which minimize pre and post needle attrition. They will accomplish this by: ensuring a mix of viable sites of care are available in the local marketplace, **educating practices on appropriate efficiency practices to infuse the pharmaceutical product(s) to remain viable, updating practices on key private and public payer changes that impact infusion process**, ensure staff in infusion clinics have been trained using company approved materials to deliver pharmaceutical product(s) in a safe and efficient manner, educate providers on patient assistance programs that are available to assist patients financially. … **The ABS approaches each customer from a total account management perspective, by leveraging resources appropriately, collaborating with business partners and accurately articulating the value proposition for the customer.**
>
> … [The ABS] **will mentor doctors and staff on how to develop and implement an In Office Infusion program including overall operations management, scheduling, staffing, pre-authorization, reimbursement, capacity management, inventory management, and infusion management/efficiencies.** The ABS will have responsibility for training appropriate clinical staff re: technical aspects of infusing the pharmaceutical product(s) including reconstitution, admixture, administration, monitoring, and adverse event management and reporting. **The ABS will serve as a resource to territory's accounts and Janssen Biotech staff regarding local, regional and national payer policies; reimbursement regulations and processes (i.e., eligibility and benefit verification, pre-authorization, billing, coding, claims, and appeals/grievances); practice management; Medicare and Medicaid rules and regulations; OSHA; HIPAA; and state-specific clinical staff licensing /certification requirements for product compounding, admixture, administration and monitoring**.

(available at https://www.linkedin.com/jobs/view/13989112 (last viewed on Oct. 12, 2016)

(emphasis added)).

117. In a 2005 internal document, Centocor included among the "essential functions" of the ABS's supervisor, the Regional Business Manager:

> Serve as a resource to region's accounts and Centocor staff re: local, regional and national payer policies; reimbursement regulations and processes (i.e., eligibility and benefit verification, pre-authorization, billing, coding, claims, and appeals/grievances); practice management; and efficiency.

118. Relator's territory action plans identified the following practice management goals among others:

- "Infusion operations are maximized," and
- "All Centocor value added services are being utilized within the practice."

119. The following letters of reference that were written on Relator's behalf illustrate Janssen and its ABSs' close involvement in the management of top Remicade and Simponi ARIA accounts[8]:

(a) A November 2015 letter of reference from Physician A who is an owner of a practice with an infusion suite that Relator helped to establish and then grow into what is now a substantial profit center for the practice:

> I am writing to you on behalf of [Relator]. I have had professional contact with [Relator] over the past 13 years. I am [a] Rheumatologist for [Account A] and have served in this capacity since July of 2002. Shortly after starting with my company I had the privilege to meet [Relator].
>
> Many representatives have crossed my path from many companies over the years. [Relator] has been a constant and has been critical to my ability to do my job effectively. **[Relator's] skill, knowledge, and professionalism has been an asset to my practice in many aspects. [Relator's] business knowledge and background in infusion helped streamline my center to be more cost**

[8] Relator has provided to the government the actual names of "Physician A" and "Account A" referenced in this paragraph.

> **effective, structured, and provided needed educational support for staff and patients.**
>
> If I had any questions no matter how big or small, [Relator] was always available and would follow through on all tasks requested. [Relator] maintained the highest level of professional deportment when interacting with myself and my staff. [Relator] always made [Relator's] goals clear, concise, and within industry standards of professionalism. [Relator] is held in the highest regard not just by me, but also my staff, and the administrators who have interacted with [Relator] as well.
>
> My only hardship would be losing [Relator] to another position within your company. My loss would certainly be your gain. [Relator] will be missed by many in the arena of Rheumatology and Infusion. I have no reservations for recommending [Relator] for your team.

(Emphasis added).

(b) An October 2015 letter of reference from a Janssen sales manager:

> [Relator] and I have developed a professional relationship at Janssen for over eight years in [Relator's] Area Business Specialist role. During this time, we have also established a personal friendship, as well as a professional business partnership with our common customers. [Relator's] territory success has come largely in part to [Relator's] strong business acumen and work ethic. [Relator's] strongest attribute, that I've witnessed, is [Relator's] commitment to the customer approach to business. **Customers trust [Relator] to get their problems resolved.** This is the core to [Relator's] success. **[Relator] is able to combine selling skills with providing value to her customers** and her crossover teams. [Relator's] customers have developed strong bonds with [Relator], recognizing that [Relator] has integrity and provides them with more than what is in [Relator's] best interest. [Relator's] colleagues, including myself, routinely call on [Relator] to provide insight, clarification, and help when solving issues for difficult customers and situations. [Relator] manages this with professionalism and never misses a stride with [Relator's] own customers, both internally and in the field. …

(Emphasis added).

120. Demonstrating the value of the skills and knowledge they receive while working at Janssen, many ABSs became practice management consultants after leaving Janssen.

2. *Each year Janssen helps hundreds of rheumatology and gastroenterology physician practices across America establish an in-office infusion suite*

121. When rheumatology and gastroenterology practices elect to follow Janssen's advice and open an in-office infusion suite, Janssen's ABSs, who are experts at opening infusion suites, assist physician practices with designing and setting-up the infusion suites and ensure that the infusion suite opens quickly (within approximately six weeks) and with as little expense and burden on the practice as possible.

122. The below "Efficiency Checklist," which Janssen first provided to ABSs in or around 2003, sets forth the various operational and practice management issues on which Janssen advises and educates physician practices (free of charge) leading up to and following the opening of an in-office infusion suite:

Account Name:	**Date:**	
EFFICIENCY CHECKLIST		
	Y/N	**Comments**
ACCESSONE		
Uses AccessOne		
BAA [business associate agreement] signed		
LOS [limitation of services]signed		
Aware of Site Coordinators name and extension		
Utilizes fax BIF [benefits investigation form]		
Utilizes e-BIF		
Maintains a BIF log or filing system		
Enrolled in Care Coordination		
Enrolled in Prior Authorization Monitoring		
Reviews Verification of Benefits when received		
Does someone discuss financial responsibility with patient		
Is there a signed financial agreement or patient contract in place		
Office aware of Patient Affordability Options		
Recertification process in place-who owns the process		
Tracking mechanism to obtain a prior authorization		
Prior auth form or prior auth monitoring checked on BIF		
Tracking mechanism for following when a PC [primary care] referral is required		
Accepts referrals from other practices		
Enrolled in 2infuse.com		
Requirements for referring patients-MD order, tests, documentation		
PATIENT AFFORDABILITY OPTIONS		
Office aware of Patient Affordability Options		
JJPAF, Foundations, Remistart		

Is office part of the Remistart Closed Network		
Does office provide Remistart enrollment form as needed		
Is office utilizing the Remistart Provider Report on e-bif		
Does office submit EOB's [explanation of benefits] for the patient or require the patient to complete		
SCHEDULING		
Who owns the schedule-Infusion Staff, Front Desk		
Patient scheduled timely after verification received		
Maintenance patients scheduled for multiple appointments		
Opportunity to run IOM [In-Office Modeler]		
Patient scheduled for next appointment prior to leaving		
Postcard/email/text appointment reminders		
Implement charges for no-shows		
INVENTORY MANAGEMENT		
Practice has recently evaluated purchase options		
Practice has recently evaluated purchase terms		
Practice has single individual responsible for ordering		
Practice has single individual responsible for receipt and storage of drug		
Drug counted and checked against invoice prior to storage		
Inventory tracking method in place and followed		
Practice orders timely to decrease inventory on hand		
Emergency drug procurement procedure established		
Practice has policy in place for SPP [specialty pharmacy] Patients		
Practice using SPP tools and resources		
Rider policy on Property Insurance for inventory		
Is the Rider policy reviewed prn and adjusted for growth		
Refrigerator is secure and of sufficient size-Location safe and locked		
Surge protector on refrigerator or connected to back up generator		
Temperatures monitored and log maintained		
Food stored in separate refrigerator		
ENVIRONMENTAL ISSUES		
Infusions occur in separate room		
Infusions chairs are appropriate for infusion-material able to be cleaned easily? Are larger chairs available for obese patients?		
Is there an area to move a patient if a reaction occurs? Curtains?		
Television/Reading material present for patients		
WiFi available		
Sharps containers are used for storage of waste		
Biohazardous waste management process is in place		
INFUSION/WORKFLOW		
Patient scheduling process is in place and followed		
Patient is called 24-48 hrs prior to infusions-assessment performed?		
Staff is trained		
Clinical competency is assessed routinely		
Capacity is sufficient for future growth:		
Number of trained staff		
Number of days		
Number of chairs		
Back-up staff identified and trained		

Cancellation process established		
Alternate sites established		
CHART/DOCUMENTATION		
Separate paper chart or EMR section (or chart section)		
HAQ/Rapid 3/DAS score incorporated into evaluation		
Infusion Documentation:		
Utilizing Janssen Biotech Infusion Flow Sheet or EMR [electronic medical record]		
Diagnosis code appropriate		
Physicians order in chart/Are orders updated PRN [whenever necessary]?		
Documentation as per Payer Policy-DMARD failure, MTX [methotrexate]		
Pre-screening questionnaire prior to each infusion		
Infusion flow chart present and contains the following:		
Wt		
Dose (is wastage documented) - JW Modifier		
Allergies		
Infection evaluation		
PPD testing / Hep B testing/ Quantaferon Gold		
Catheter Placement-Site/Gauge/Length of Catheter/# of Attempts/Removal		
Lot # / Exp Date		
Vital signs (initial and ongoing)		
Premeds		
Protocol Available		
Infusion Start and Stop Times		
S/E –ADR [side effect management and advanced directives]		
Check local/state licensure requirements-RN/LPN/MA		
Check state board of medicine for requirements-Does MD need to sign verifying correct reconstituted amount for LPN/MA?		
Clinical signature		
BILLING		
Remicade Tracking log in place		
Process in place and followed to capture all infusion charges		
Cross check infusion schedule with infusions billed		
Prior auth/Pre-cert process in place and followed		
Collection policy in place		
Patient copay collected up front		
Medicare non coverage policy signed-ABN [assignment of benefit notification] available?		
Current Price loaded for Remicade-Someone assigned to track changes?		
Electronic claims filed		
A/R [accounts receivable] aging report reviewed appropriately		
Separate cost center / Bank account established for Remicade		
Individual identified to follow up on outstanding claims		
Adequate computer software / alternate system		
Denied claims appeals process initiated timely		
Is office aware of AccessOne's Appeal Process-administrative appeals only		
Denied claims follow-up/responsibility		
CONTRACTS		
Yearly review of Contracts (does the contract address IOI [in-office infusion])		

Review reimbursements captured to ensure contracts are being honored		
Advocates in the local Market		
Insurer Policy Summary Sheet utilized		
Copies of Contracts on file		
MBPO PROCESS IN PLACE		
Routine MBPO [Managing Biologics in the Physician's Office presentation] scheduled		
PAYING INVOICE		
Terms of invoice followed		
Terms negotiated on a regular interval-discounts available? Longer terms?		
PATIENT EDUCATION		
Education Documented		
Patient provided Remicade information - informed consent		
Medication Guide shared		
Discharge information provided		
Patient provided education materials		

123. ABSs spend a consultative session covering each section of the checklist (a few sections can be combined into one consultative session). ABSs usually become entrenched in the physician practices and end up working side by side with the practice manager and office staff in actually accomplishing many of the tasks on the checklist.

124. Relator estimates that each year Janssen's ABSs help hundreds of rheumatology and gastroenterology practices across the country start an in-office infusion business.

3. *After helping rheumatology and gastroenterology practices establish in-office infusion suites, Janssen regularly provides free practice management services to induce them to prescribe and infuse Remicade and Simponi ARIA*

125. If a physician practice cannot operate its infusion suite profitably, then it will likely switch from prescribing and infusing Remicade and Simponi ARIA to prescribing the Self-Injectables or other biologics that come in tablet form, both of which are easier to prescribe as they are not subject to the same level of insurance coverage prerequisites and involve no additional practice expense. As Janssen often tells physician practice accounts to which it provides free advisory and practice management services, "if you are upside down on the drug you will not use it."

126. The importance and value of Janssen's provision of free practice management services to increase the efficiency and profitability of in-office infusion suites – and thus the sales success of Remicade – has grown over time because Medicare has lowered the amount it pays physician practices for Remicade while increasing the amount it pays for infusion services.

127. Thus, in order to ensure that rheumatology and gastroenterology practices profit from their infusion suite, Janssen provides ongoing, free practice management advice and services and is always available to help address any business issues that these practices confront. By ensuring that a rheumatology and gastroenterology practice's infusion suite becomes a major profit center, Janssen creates a powerful economic incentive for the practice to continue prescribing and infusing Remicade and/or Simponi ARIA rather than prescribing less profitable Self-Injectables or biologics taken orally.

128. Moreover, since these providers reap substantial economic benefits from Janssen's ongoing free practice management services, they want to maintain their partnership with Janssen so as to continue receiving the valuable free services. As a result, the practices also generally choose Remicade and Simponi ARIA over other biologics that are delivered through infusion.

129. In fact, Janssen's strategy is to cause rheumatology and gastroenterology practices to become dependent on the revenue from Remicade and Simponi ARIA infusions because these practices will then be more likely to continue buying and infusing these drugs. Indeed, Janssen has helped many of its top accounts grow and develop their infusion businesses exponentially so as to create high volume in-office infusion suites, which Janssen sometimes internally refers to as "cash cows" and "Remicade mills."

130. Janssen's kickback scheme has been highly effective at increasing sales of Remicade and Simponi Area while sustaining the infusion business model. Rheumatology and gastroenterology physician practices that have received Janssen's free assistance in establishing and operating their infusion businesses predominantly use Remicade and Simponi ARIA. By comparison, physician practices that do not have an infusion suite generally prescribe all of the biologics – Remicade, Simponi ARIA, other infusibles, Self-Injectables, and oral biologics.

131. Said differently, Janssen's kickback scheme influences and indeed corrupts the treatment decisions of the rheumatology and gastroenterology practices with infusion suites that are administering Remicade and/or Simponi ARIA to high volumes of unsuspecting patients, including Medicare and Medicaid beneficiaries.

132. Self-Injectables and biologics that come in tablet form can be administered far more quickly and conveniently, as patients can self-administer these drugs in their home. Remicade and Simponi ARIA, on the other hand, are delivered through lengthy infusions performed at medical facilities every eight weeks for long stretches of the patients' lives. Additionally, infusion procedures can be difficult on the body. Patients often feel fatigued and weak afterwards, requiring them to rest to recover from the procedure.

133. Consequently, by influencing hundreds if not thousands of health care providers to prescribe Remicade and Simponi ARIA instead of equally effective Self-Injectables and biologics that are taken orally, Janssen is causing these very sick patients, many of whom are immobile or struggle moving from place to place, substantial inconvenience and discomfort while also exposing them to the drugs' potential harmful side effects.

134. Importantly, Janssen attempts to disguise its long-running, pervasive business advisory and practice management services kickback scheme as merely a method of making sure

that patients have access to an infusion suite where they can receive Remicade and Simponi ARIA. However, there is no shortage of health care facilities and providers who offer infusion services. In reality, Janssen is completely disregarding patients' best interests, and is indeed inconveniencing them and exposing them to potential harm, in order to increase sales of Remicade and Simponi ARIA by corrupting rheumatologists' and gastroenterologists' treatment decisions. Janssen gets physicians hooked on the significant passive income that can be made from infusing Remicade and Simponi ARIA so that whenever possible the practices prescribe these Janssen products instead of non-biologic therapy, competing Self-Injectables, such as Humira, Enbrel, and Cimzia, other infusibles, and competing biologics that can be taken orally.

135. Janssen closely tracks Remicade and Simponi ARIA prescriptions, sales and infusion volume among rheumatology and gastroenterology practices in the in-office infusion market. Typically, Remicade's and Simponi ARIA's top customers are physician practices that have developed, with Janssen's close assistance, infusion businesses that perform the highest volume of infusions in their respective region. To reward those accounts in each territory that purchase and infuse the highest volume of Remicade and Simponi ARIA and to induce them to continue to grow their usage of the drugs, Janssen visits these physician practices at least once per month to provide free practice management services. The second tier of customers in terms of Remicade and Simponi ARIA sales are rewarded with at least one on-site practice management consultation per quarter. The third tier of customers receive at least one on-site practice management consultation per year. Physician practices that do not prescribe and infuse Remicade or Simponi ARIA and accounts where the sales volume is relatively low do not receive any free business advisory services unless they express an interest in growing their infusion business and show a commitment to prescribe and infuse Remicade and Simponi ARIA,

in which case Janssen helps them develop and grow their infusion business. In this regard, each quarter the ABSs select several accounts in their territory that they believe could grow their usage of Remicade and/or Simponi ARIA and provide these accounts free business advice and practice management services.

136. Since Janssen has already helped top rheumatology and gastroenterology practices build infusion profit centers and turn them into well-oiled machines and highly-profitable enterprises, most of the top accounts are already fairly well versed in most of Janssen's practice management services. It is the rheumatology and gastroenterology practices that are operating a new or fairly new in-office infusion business that benefit from the free practice management services the most and correspondingly express the highest interest in these services.

137. Examples of the types of practice management services that Janssen provides to top rheumatology and gastroenterology customers include, among others:

(a) ***Infusibles over Self-Injectables (Remicade or Simponi ARIA over Humira)*:** Using its analytical program called "IBiz" (short for infusion business), Janssen shows rheumatology and gastroenterology customers how they can increase their profits by using infusible biologics – namely Remicade or Simponi ARIA – instead of the Self-Injectables, such as Humira, Enbrel, or Cimzia, or other biologics taken orally, such as Xeljanz. Janssen starts by having the practices provide their prescription data for the period. It then analyzes the data and shows the customer how much infusion service revenue the top accounts forsake by prescribing certain patients a Self-Injectable or oral biologic. Since 2008, Janssen has been providing the IBiz consultation service to tier 1 accounts once per month and at least quarterly for tier 2 accounts. It is left to the ABSs' discretion as to how often Tier 3 accounts receive free practice management services. ABSs focus mostly on tier 3 practices that show a potential for growth or

specifically request services to help them grow. Through an analysis it calls the "physician dashboard," Janssen similarly reviews each individual practitioner's biologic usage history so the physician practice knows which individual physicians are costing it revenue by prescribing Self-Injectables or oral biologics rather than Remicade or Simponi ARIA. In addition, Janssen compares the practice's average usage of Remicade and Simponi ARIA to the national average for the drugs. If the practice is lower than the national average, Janssen advises that the practice should be more aggressive in prescribing and infusing Remicade and Simponi ARIA.

(b) ***Efficient scheduling and minimizing costs*:** Janssen advises top accounts how to maximize their profits by managing their infusion schedules more efficiently so as to perform all infusions in a shorter period of time while minimizing the practices' overhead costs, namely nurse coverage (physician practices that operate infusion suites typically pay a nurse an hourly fee to insert and remove the IVs). Using its analytical program called the "In-Office Modeler," or "IOM," Janssen reviews top accounts' infusion schedules and instructs them how to stagger infusion start times to perform all infusions during a set number of days and provides a schedule optimization plan. Janssen also monitors to ensure that accounts implement the infusion optimization plan. Janssen has ABSs perform the In-Office Modeler for tier 1 accounts at least monthly and at least quarterly for tier 2 accounts. Janssen has been providing this free service to top rheumatology and gastroenterology accounts since around 2008.

(c) ***Switching from Remicade to Simponi ARIA*:** Knowing that Remicade's exclusivity rights are set to expire soon, when Simponi ARIA was approved in July 2013, Janssen began advising top rheumatology accounts that they will increase their infusion revenue by administering Simponi ARIA instead of Remicade. Likewise, to induce physician practices to use Simponi ARIA instead of Remicade, through its CPP program (*see* Part V-A-3 above),

Janssen offers physician practices a larger discount on Simponi ARIA than Remicade. In addition, since the time of infusion for Simponi ARIA is 30 minutes compared to 120 minutes for Remicade, Janssen advises rheumatology practices that if they use Simponi ARIA rather than Remicade and appropriately schedule the patients they can perform three times as many infusions in a day. And since Medicare reimburses significantly more for the first hour of an infusion than the second hour, as illustrated by the chart below, the practices' infusion suites can earn more revenue per day by performing more 30-minute Simponi ARIA infusions than two-hour Remicade infusions.

Comparison of Infusion Service Reimbursement for Remicade vs. Simponi ARIA (2013 Physician Fee Schedule Rates for Massachusetts (Excluding Metropolitan Boston Area))			
	Daily Infusions Per Chair	**Infusion Service Reimbursement**	**Daily Infusion Service Revenue Per Chair**
Remicade (2 hr. infusion)	4	$183 (1st hr. $151+ 2nd hr. $32)	$732
Simponi ARIA (30 min. infusion)	12	$151	$1,812

The below excerpts from Relator's February 2015 monthly performance evaluation report written by Relator's manager shows how Janssen is aggressively advising accounts to switch from Remicade to Simponi ARIA before Remicade's patent expires[9]:

> Get to … person we spoke to from [Account A] this week and have her see the value that Simpono aria [sic] makes to the infusion center/ Proactively [Relator] is asking for more exposure on [Relator's] endeavors on how [Relator] is having [Relator's] practices in their territory to circumvent the payer policies in [the territory].
>
> * * *
>
> [Physician B] needs to hear more drive for Simponi ARIA…..Expalin [sic] and document for him the need to drive more Arai [sic] in his infusion center. Ask for more (2) new patients per week. Use you trigger report and ask for the business. … [G]rowth and advancement of SA will drive your overall performance[.]

[9] Relator has provided to the government the actual names of "Account A" and "Physician B" referenced in this paragraph.

In instructing Relator to "explain and document" to this rheumatologist "the need to drive more [Simponi ARIA] in his infusion center," the manager was directing Relator to use the IBIZ and IOM to show the physician how he can generate more revenue by prescribing and infusing Simponi ARIA rather than Remicade or other competing biologics. Demonstrating the impact of Janssen's advice about switching from Remicade to Simponi ARIA to top accounts, the ratio of Simponi ARIA sales to Remicade sales is much higher among rheumatology accounts that receive Janssen's free practice management services than those that do not receive such services.

(d) ***Infusion suite set-up and décor*:** Janssen provides top rheumatology and gastroenterology practices with free advice regarding the optimal design and organization of their infusion suites so as to fit in as many infusion chairs as possible and in turn optimize scheduling to maximize the infusion suites' profitability. If patients find an infusion suite to be aesthetically pleasing and comfortable, they will pay more and travel further to receive their infusions there. Accordingly, Janssen assists top customers by providing design and décor advice, often making infusion suites feel like a spa experience. This advice helps top customers ensure retention of their current infusion patients, most of whom receive Remicade and Simponi ARIA infusions, as well as attract new patients. Janssen also helps top accounts survey patients to learn about their infusion experience. Janssen calls this service "RISE," which stands for "Raising Infusion Suite Experience," and ABSs provide the service whenever they believe the practice will benefit from it.

In an internal document prepared by Janssen's compliance group, the Company essentially acknowledged that this service constitutes a kickback:

> **SCENARIO: A customer is considering expanding/reconfiguring their office space to better accommodate their IOI patients. They would like to know when they could expect a return on their investment. Can we provide such information to the physician through a cost analysis or otherwise?**

- No…You cannot directly or indirectly provide consulting services to a physician's office that are part of the physician's general overhead. You may not assist a particular physician with assessing his cost of expansion, nor should any guarantee of payment be made to tell the physician when he or she will recoup his or her costs of expansion.

(e) ***Negotiating higher reimbursement rates from commercial payers*:**

Janssen provides top rheumatology and gastroenterology practices free advice on how to negotiate contracts with commercial payers to obtain the highest reimbursement for Remicade and Simponi ARIA, infusion services, as well as other frequently billed drugs and services. Traditionally, most physician practices allow their contracts to automatically renew without attempting to increase their reimbursement rates. These auto-renewing contracts are referred to as "evergreen contracts." Janssen advises top practices to terminate the auto-renew provision so they can negotiate higher reimbursement rates. Janssen also advises these top accounts how to evaluate their contracted payment rates for the practices' high volume services and drugs. Janssen provides the practice manager a payer summary sheet for each commercial payer with which the practice has a contract. The practice manager then contacts each commercial payer to determine the practice's current contracted rates for Remicade and Simponi ARIA, the infusion services (codes 96413 and 96415), and other services and drugs. Janssen also helps the top accounts enhance their practice profile going into their negotiation by addressing items that the commercial payers often consider in setting rates, such as the practice's quality of care metrics, patient satisfaction scores, staff expertise, referral times, convenience, patient parking access, offering weekend hours, wait times, and efficiency of infusion procedure (total time in the infusion suite). Janssen's RISE program (*see* subparagraph (d) above) frequently helps top accounts receive higher reimbursements on Remicade and Simponi ARIA and infusion services. When accounts show the commercial payers that their infusion patients give them high

satisfaction scores, the insurance companies often agree to increase the reimbursement rates on infusions. In addition, Janssen helps outline negotiation strategies that top accounts can use to obtain better rates from commercial payers. As with other practice management services, Janssen frequently contracts with an outside consultant, often Xcenda, to educate top accounts about negotiating higher reimbursement rates with commercial payers, paying over $1,200 per consultative session.

In an internal document prepared by Janssen's compliance group, the Company essentially acknowledged that providing this service for free constitutes a kickback:

> **SCENARIO: A practice administrator has asked me to review the practice's managed care contracts and to assist the practice in renegotiating their contracts. Can I provide this support to the practice, or arrange for a consultant to provide such services to the practice?**
>
> - No…You cannot directly or indirectly provide free services to a physician's office that are part of the physician's general overhead.
>
> - The office manager should be advised that there are many consultants or attorneys who could assist them in renegotiating their contracts for a fee. Industry societies or associations may also be able to assist them with a referral to such professionals.

(f) ***Obtaining coverage of Remicade and Simponi ARIA*:** Because of their steep price and the additional cost required to administer the drugs via infusion, many commercial payers require prior authorization of infusible biologics like Remicade and Simponi ARIA. In fact, as discussed in paragraph 97 above, many commercial payers and certain Medicaid plans have a step therapy requirement under which they will only cover Remicade and Simponi ARIA if the patient is unable to take or does not respond to a Self-Injectable. Inasmuch as non-compliance with these coverage prerequisites can result in payment denials, Janssen educates top accounts on strategies to convince insurers to waive step therapy requirements. At the same time, Janssen organizes lobbying campaigns in which physicians as well as

rheumatology and gastroenterology foundations (*e.g.*, the American College of Rheumatology, Crohn's & Colitis Foundation of America, and National Organization of Rheumatology Managers) argue that the insurance companies should not restrict physicians' use of Remicade and Simponi ARIA through step therapy requirements. In addition, Janssen helps top practices develop a streamlined process for seeking prior-authorization for Remicade and Simponi ARIA, which the Company considers to be essential to the operation of a profitable infusion suite. It coaches the physician practices that when pre-approval is denied they should appeal multiple times and demand peer-to-peer reviews. Again, Janssen does not charge for these services.

Moreover, Janssen advises top practices to utilize AccessOne, an outside service offered by the Lash Group and paid for by Janssen, to assist with obtaining prior authorization requests because AccessOne is proficient in obtaining prior authorizations from commercial payers and Medicaid plans.[10] Janssen's ABSs act as a liaison between the physician practice and AccessOne, collecting the patients' information from the physician practice and providing it to AccessOne. The AccessOne service is highly valuable because it makes it much less burdensome and time consuming for practices to obtain prior authorization for Remicade and Simponi ARIA infusions. In addition, Janssen educates top accounts that commercial payers that have a step therapy coverage requirement will cover Remicade and Simponi ARIA if the physician reports that the patient (i) could not self-inject Humira, (ii) is not responding to Humira, (iii) has a fear of needles, or (iv) is not performing the injections at the required intervals.

Janssen informed ABSs that, as a result of these various efforts to blunt step therapy and prior authorization requirements for Remicade and Simponi ARIA, insurance

[10] Janssen recently changed the name of the AccessOne service to CarePath.

companies that impose such requirements nevertheless approve, on average, 70% of Janssen's customers' requests for coverage of Remicade and Simponi ARIA.

(g) ***Appeals of coverage denials*:** One of the most common reasons for a coverage denial is that the patient did not attempt to use a Self-Injectable, such as Humira, before being treated with Remicade or Simponi ARIA. ABSs advise top accounts that denials can be overturned by filing an exception or appeal. Janssen pays the Lash Group's AccessOne service to assist its rheumatology and gastroenterology practice accounts appeal coverage denials. Janssen advises top accounts to utilize the AccessOne service rather than handling appeals directly, as it reduces the practice's overhead costs – physician practices frequently employ individuals to handle coverage issues with payers – and AccessOne is adept at overturning coverage denials. Janssen also tells the accounts that the AccessOne service does not cost them anything. Here again, Janssen's ABSs act as a liaison between the physician practice and AccessOne by reviewing verification of benefit forms (patient specific information is redacted) completed by AccessOne to assist the practice with obtaining coverage and payment.[11] The AccessOne service is highly valuable because it makes it much less burdensome and time consuming for practices to appeal Remicade and Simponi ARIA coverage denials.

(h) ***Other free practice management services and business advisory programs that Janssen regularly provides to top rheumatology and gastroenterology practices*:**

- Help establishing infusion and nursing protocols to compliment the infusion service line – this is normally the responsibility of the practice's nurse manager;
- Help establishing standing orders regarding the administration of Remicade and Simponi ARIA – this is normally the responsibility of the practice's nurse manager;

[11] Prior to a Janssen policy change in 2014, ABSs would further assist top accounts by talking them through how to complete a letter of medical necessity and appeal forms while the practices completed the forms.

- Advise on billing practices and strategies that ensure maximum reimbursement from government and commercial payers while avoiding audits;

- Advise on regulations and laws concerning the operation of infusion suites and billing for infusions;

- Assist with implementation of electronic medical record systems that collect and analyze quality of care metrics that can be used to obtain Medicare bonuses and negotiate higher reimbursement rates from commercial payers;

- Advise on establishing standard operating procedures to improve practice workflow – drug eligibility and benefit verification, pre-authorization, billing, coding, claims, and appeals – and ensure maximum usage of infusible biologics, namely Remicade and Simponi ARIA;

- Assist with improving financial management related to the acquisition of Remicade and Simponi ARIA;

- Informing practices of government and commercial payer policy changes that impact their infusion businesses;

- Advise on managing the inventory of biologics with a heavy emphasis on Remicade and Simponi ARIA;

- Advise on maximizing collection of co-payments from patients who receive Remicade, Simponi ARIA, or other biologic infusions and training on how to coach patients to obtain financial assistance from foundations and programs to cover the substantial co-pays;

- Encouraging practices to take advantage of Janssen's infusion suite locator – 2infuse.com – to increase the practices' profile and attract referrals;

- Advise on local, regional and national payer policies;

- Advise on Medicare and Medicaid rules and regulations;

- Advise on compliance with applicable Health Insurance Portability and Accountability Act ("HIPAA") and Occupational Safety and Health Administration ("OSHA") laws and regulations;

- Advise on state clinical staff licensing/certification requirements for infusion administration and monitoring;

- Advise on how gastroenterologist practices can perform infusions in an ambulatory surgery center ("ASC") space[12]; and
- Other infusion suite business issues referenced on the Janssen checklist set forth at paragraph 122 above.

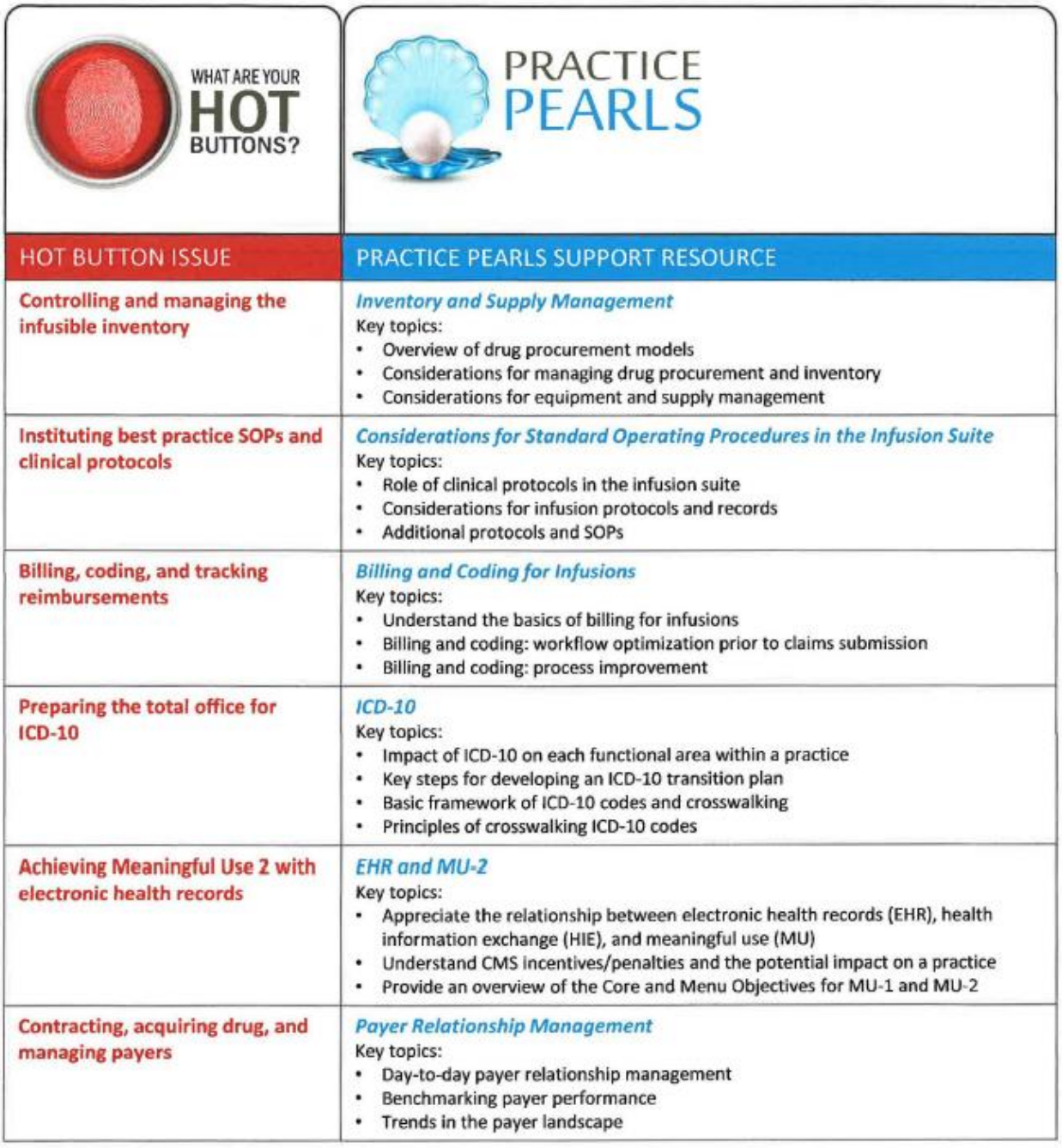
138. Since 2015, Janssen has been utilizing a tool through which it provides rheumatology and gastroenterology practice owners and managers a list of "Hot Button Issues" from which they can select the practice management program, referred to as "Practice Pearls," that they want to receive from the Janssen ABS during their current consultative session. Most of these presentations are designed to ensure and increase Remicade and Simponi ARIA infusions while simultaneously creating an opportunity for discussions during which the ABSs reinforce the economic benefits of using the drugs. The menu of "Hot Button Issues" and related "Practice Pearls" is appended below:

[12] Janssen has been paying outside consultant Christine Pierce from The Resource Group to advise top gastroenterology accounts on using their ASC space for infusion services for approximately ten years. Starting in or around 2010, Janssen also had ABSs advise gastroenterology practices regarding utilization of their ASC space for infusions. Due to concerns over potential liability issues if the infusion services and ASC services are not properly segregated, Janssen stopped having ABSs advise on this topic in 2013 and now strictly pays The Resource Group to provide this advisory program to its customers free of charge.

Hot Buttons identifies and prioritizes customized operational support needs within a practice.

Once these needs have been identified, the interactive educational program, Practice Pearls, can be used to provide customized support.

HOT BUTTON ISSUE	PRACTICE PEARLS SUPPORT RESOURCE
Optimizing your prior authorization/benefit investigations workflows	***Prior Authorizations and Benefit Investigation Workflow Optimization*** Key topics: • Medical benefit product preferencing • Prior authorization and benefit investigation: optimization • Prior authorization and benefit investigation: process improvement
Communicating concepts of affordability (commercial plans and Medicare) to patients	***Navigating Affordability in Commercial Plans and Medicare*** Key topics: • Define common benefit terminology • Discuss differences in commercial and Medicare coverage • Understand pharmacy and medical benefits from a practice perspective • Determine roles and responsibilities in your practice
Utilizing alternative approaches to mitigate risk with buy-and-bill	***In-office Infusion Drug Procurement Models*** Key topics: • Overview of drug procurement models • Process workflows for drug procurement models • Considerations for managing drug procurement and inventory
Enhancing the continuity of care with inbound and/or outbound referrals	***Infusion Referrals: Improving the Continuity of Care*** Key topics: • Common gaps in infusion referrals • Process for quality improvements in referral care coordination • Assessing referral care coordination
Optimizing patient scheduling and infusion capacity	***iBiz/IOM***
Enhancing quality measures, patient experience, and satisfaction	***Quality of Care in the Infusion Suite*** Key topics: • Factors that affect quality across the continuum of care • The role of quality of care in today's healthcare environment • Why you should care about quality of care



HOT BUTTON ISSUE	PRACTICE PEARLS SUPPORT RESOURCE
Controlling and managing the infusible inventory	***Inventory and Supply Management*** Key topics: • Overview of drug procurement models • Considerations for managing drug procurement and inventory • Considerations for equipment and supply management
Instituting best practice SOPs and clinical protocols	***Considerations for Standard Operating Procedures in the Infusion Suite*** Key topics: • Role of clinical protocols in the infusion suite • Considerations for infusion protocols and records • Additional protocols and SOPs
Billing, coding, and tracking reimbursements	***Billing and Coding for Infusions*** Key topics: • Understand the basics of billing for infusions • Billing and coding: workflow optimization prior to claims submission • Billing and coding: process improvement
Preparing the total office for ICD-10	***ICD-10*** Key topics: • Impact of ICD-10 on each functional area within a practice • Key steps for developing an ICD-10 transition plan • Basic framework of ICD-10 codes and crosswalking • Principles of crosswalking ICD-10 codes
Achieving Meaningful Use 2 with electronic health records	***EHR and MU-2*** Key topics: • Appreciate the relationship between electronic health records (EHR), health information exchange (HIE), and meaningful use (MU) • Understand CMS incentives/penalties and the potential impact on a practice • Provide an overview of the Core and Menu Objectives for MU-1 and MU-2
Contracting, acquiring drug, and managing payers	***Payer Relationship Management*** Key topics: • Day-to-day payer relationship management • Benchmarking payer performance • Trends in the payer landscape

139. Janssen's ABSs provide the various practice management and business advisory services during consultative sessions with practice managers, practice owners, and office staff that typically last approximately three hours. Before an ABS is permitted to present on a particular practice management topic, Janssen educates the ABS on the topic, trains the ABS on

how to present the information to physician practice accounts to drive Remicade and Simponi ARIA infusions, and requires the ABS to pass a test to become certified on the presentation.

140. All of the practice management services that the rheumatology and gastroenterology practices receive free of charge from their "business partner" Janssen help them operate more profitably by increasing the revenue from their in-office infusion suites while also helping the practices to reduce their overhead costs. Notably, although Janssen provides the free practice management services to induce utilization of its products, the practice management information and advice that Janssen provides apply equally to other infusible drugs and services, and even general administrative functions, and thus help the practices more efficiently and profitably manage other aspects of their businesses far beyond the prescription and infusion of Remicade and Simponi ARIA.

141. Specific examples of physician practices for which Relator helped establish in-office infusion suites and helped grow their infusion businesses (and Remicade and Simponi ARIA sales) by providing regular free practice management and business advisory services include[13]:

(a) In or around 2008, Relator provided the practice management programs discussed above to help Account A create a new state-of-the-art infusion suite with six infusion chairs. At this multi-specialty practice, the rheumatology group prescribes and infuses Remicade and Simponi ARIA and the gastroenterology group prescribes and infuses Remicade. Under the practice's structure, the gastroenterology group purchased Remicade through the rheumatology group. In or around 2011, the practice requested that Relator assist the practice in determining

[13] Relator has provided to the government the actual names of "Account A," "Account B," "Account C," "Account D," "Account E," "Account F," "Account G," and "Hospital A" referenced in this paragraph.

the source of financial shortfalls in its infusion suite. Upon investigation and using the Janssen efficiency checklist it was discovered that:

- Different employees provided the back office support for the rheumatology and gastroenterology groups and these employees did not understand their role and responsibilities with regard to the infusion service line;
- The billing department was not using the appropriate infusion service and Remicade and Simponi ARIA codes;
- The practice was not collecting the 20% co-pay for infusions of biologics provided to Medicare beneficiaries;
- There was no internal audit system in place to ensure that the billing system was functioning properly and payers were paying the contracted rates for infusion services and drugs;
- The practice did not have infusion protocols in place;
- Encounter sheets had not been updated;
- The gastroenterology group sent patients to the rheumatology group, which purchased the biologics, for infusion services. The reimbursements for the biologics were divided equally between the gastroenterology and rheumatology, causing the rheumatology group to sustain a loss on each purchase; and
- The practice was not tracking biologics obtained from a specialty pharmacy to distinguish them from biologics acquired through buy-and-bill methodology, causing the practice to not bill for thousands of dollars' worth of biologics acquired through buy-and-bill methodology.

Relator helped the practice address all of these operational problems and return its infusion suite to profitability. In terms of sales volume growth, the practice's rheumatology group became one of the top accounts in the region for Remicade and Simponi ARIA sales, and the practice's gastroenterology group became one of the top accounts in the region for Remicade sales. The free business advisory and practice management services Janssen provided to this practice induced a steady increase in prescriptions and infusions of Remicade and Simponi ARIA.

(b) In or around 2013, Relator helped Account B undertake a financial analysis and feasibility study regarding the opening of an in-office infusion suite to perform Remicade infusions. Relator helped this practice open an infusion suite and train its employees on the operation of the suite and thereafter provided the practice management programs discussed above. Inasmuch as many hospitals do not profit from Remicade infusions, Relator advised Hospital A to refer all Medicare and Medicaid beneficiaries who need a Remicade infusion to Account B, helping this customer grow its in-office infusion business. The hospital has dramatically reduced the losses it was incurring on Remicade infusions, as 80% of the hospital's Remicade patients, most of whom are Medicare and Medicaid beneficiaries, in accordance with Janssen's advice, now receive their Remicade infusions at Account B as well as Account C – two large Janssen accounts. A June 2013 email from a Janssen sales representative to the district sales manager illustrates how Janssen's help in opening the in-office infusion suite at Account B induced sales of Remicade:

> [Account B] started to infuse today. [Relator] and I started this process last July when [Account B] was added to my territory. After countless hours of educational meetings, the IOI [in-office infusion suite] opened today without a flaw. We brought in Jane Clevenger from MCV[14] and she did a tremendous job with … the new infusion nurse in [Account B's] office. **For now, they are infusing all new patients with patients being infused in the hospital being added as time goes by. They currently have over 70 patients on Remicade, and so far [Account B] has added 7 new patients. With this current trend they should be adding 4-5 new patients a month.** There is great excitement within the practice and they are very proud of their IOI. The IOI has two chairs now and within the next 6 months they will be adding a third, and they have room to add a fourth when it is needed. They will be infusing every Monday and Thursday and hope to be at four days a week very soon. **Their first order was for 24 vials and they should be ordering weekly as they go forward.**

[14] MCV Associates is another outside consulting firm that Janssen pays to provide clinical training and information to rheumatology and gastroenterology practices that are opening an in-office infusion suite.

> After talking with the office at the end of the day their patients were really impressed with the facility and were very happy with the care they received during their infusion. **[Account B's] office coordinator could not thank Janssen enough. She said that they could not have opened this IOI without us.** I will be monitoring this account very closely and making sure that all their questions and concerns are answered in a timely manner. **The addition of this IOI will definitely help the … district rise to the top and help us finish number one in the Region.**
>
> I want to thank [Relator] for all [Relator's] efforts in getting this account on line with all their billing needs and making sure this IOI went off without a hitch.

(Emphasis added). The volume of Remicade prescriptions and infusions by Account B increased exponentially from 2013 to 2015 after Janssen helped the practice establish and grow its in-office infusion business. Relator's discussions with the Director of Pharmacy for Hospital A, was a significant factor in the increase in Remicade sales at Account B. The hospital was concerned with the lack of profitability on Medicare infusions and thus was interested in moving infusions "out of the hospital," to Account B, which was seeking to grow its volume of in-office infusions of Remicade. This arrangement facilitated by Janssen created a windfall for Account B's in-office infusion business and also helped Janssen by shifting business from a hospital to a loyal in-office infusion suite customer.

(c) In or around 2008, Relator helped Account D open an infusion suite at a centralized location, train its employees on the operation of the infusion business, and improve its reimbursement rates. Account D's practice administrator relied heavily on Janssen's free practice management services to enhance and grow the practice's Remicade in-office infusion business. Since 2008, the practice's sales of Remicade have grown approximately 20% annually despite many payers having single step therapy and prior authorization requirements. In addition, after Relator provided the IBIZ and IOM presentations, the practice placed an additional chair in the infusion center as well as a new nurse to improve the efficiency of its infusion business.

(d) When Account E relocated its office several years ago, the physician owners asked Relator to train the new office manager on how to maximize the practice's infusion suite's efficiency and profitability. Another example of how Relator helped this practice become more profitable and infuse more Remicade is the advice Relator provided in 2010 regarding adding a half day to its infusion schedule so as to enable the practice to perform more Remicade infusions. The practice's office manager continues to rely heavily on Janssen's free practice management services.

(e) From 2003 until Relator left Janssen, Relator provided Account F weekly consultations to educate the practice on, among other operational issues, optimization of their infusion suite, successfully negotiating better reimbursement rates and no coverage limitations for Remicade and Simponi ARIA, adoption of the Athena electronic medical record system for claim submission, education regarding infusion coding guidelines, negotiating a mixing fee into its contract with the dominant commercial payer, and development of infusion protocols. In addition, in February 2010, Relator helped this practice design a new infusion center and optimize its profitability by determining the number of infusion chairs it could manage.

(f) Account G called Janssen in early 2010 to ask for a recommendation regarding an infusion center to which it could send patients for their two-hour Remicade infusions because it wanted to use its infusion chair to perform infusions of Orencia, which last only 30 minutes compared to Remicade's two-hour infusions. Janssen analyzed the practice's Remicade and Orencia volume and created a schedule that allowed the practice to perform all infusions over two days each week, ensuring continued utilization of Remicade by the practice. Before that, relator along with an outside consultant from Xcenda, whose fees were paid by Janssen, instructed the practice on negotiating with payer contracts and ultimately helped it to

obtain more favorable reimbursement rates. Additionally, Relator helped this practice establish an infusion suite in a second location.

4. *The free practice management services Janssen regularly provides to rheumatology and gastroenterology practices have significant value*

142. Janssen's free practice management services have significant economic value because they help health care providers increase their profits and grow their businesses. Additionally, while Janssen uses its free practice management services to influence physicians' treatment decisions and induce utilization of its products, the information provided is often more general and non-branded and is applied by rheumatology and gastroenterology practices to increase their profits on other services and drugs and more effectively and profitably operate their entire businesses. The services' significant value is also evidenced by the fact that health care providers pay significant fees to consultants to receive similar practice management services. Indeed, before forming its own team of practice management consultants – or ABSs – to advise and assist physician practices with establishing and operating infusion suites, Janssen paid outside consultants to provide these services. And even after forming its own team of Business Specialists, Janssen still pays outside consultants to advise its top physician practice customers regarding emerging issues and certain more technical practice management topics, such as negotiating contracts with commercial payers to avoid prior authorization requirements for Remicade and Simponi ARIA and to help practices increase reimbursement amounts for Remicade and Simponi ARIA and infusion services.

143. For example, for as long as Relator worked at Janssen, Janssen paid consulting firms Xcenda, the Lash Group, and MCV Associates, all of which are subsidiaries of AmerisourceBergen Corporation, over $1,200 per consultative session to provide practice management advice to top accounts. An example of another consultant Janssen pays to provide

business advisory presentations to top Remicade customers is Christine Pierce, CHE, of The Resource Group.

144. Moreover, inasmuch as Xcenda, the Lash Group, MCV Associates, The Resource Group, and other outside health care consultants are businesses that rely on receiving consulting fees, they are continuously developing new programs that provide value to health care providers. Janssen pays these consultants to provide their newly developed programs to top Remicade and Simponi ARIA accounts while Janssen representatives observe. Once Janssen becomes expert regarding a practice management program topic, it creates a similar program which then becomes part of the catalogue of free programs the Company's ABSs provide to top rheumatology and gastroenterology accounts.

145. Further illustrating the value of the practice management services Janssen provides, multiple accounts asked the Relator, who was employed as an ABS, whether the Relator should sign an IRS Form 1099 from the practice.

146. The substantial profits that Janssen earns from the increases in sales of Remicade and Simponi ARIA generated by the free business advisory services more than pay for the significant cost Janssen incurs to provide these valuable services or kickbacks.

5. *Janssen knows that providing free practice management services to induce sales of Remicade and Simponi ARIA violates the Federal and State FCAs and AKS*

147. Janssen knows that a large percentage of its rheumatology and gastroenterology practice accounts' patients are Medicare and Medicaid beneficiaries and that the government health care programs are key payers for the Remicade and Simponi ARIA and the infusion services that these patients receive. Indeed, Janssen advises the practices that these are the most desirable patients because, unlike many commercial insurers, Medicare and many of the state Medicaid programs do not have any prior authorization or step therapy requirements.

148. Janssen is also fully aware that the free practice management services that are at the center of its marketing strategy for Remicade and Simponi ARIA constitute illegal kickbacks. In an internal document from 2014 entitled "Health Care Compliance – Site of Care ABS Speaker Training," Janssen recognizes that the Federal AKS **"[m]akes it illegal for pharmaceutical manufacturers to give [health care providers] anything of value to induce them to prescribe or purchase products that are reimbursed in whole or part by a federal health care program."** (Emphasis added). In this same document, Janssen also recognized that "[o]rders for prescription drugs that were induced by improper incentives or kickbacks, and later reimbursed by a federal program" violate the False Claims Act, and that "[c]ompanies/ individuals have also been held liable for claims made by [health care providers] if their conduct 'caused' a false claim to be submitted." Thereafter, Janssen openly admits through a specious warning to its employees that the very services that the Company regularly provides to rheumatology and gastroenterology practices constitute kickbacks:

> **[E]mployees may not offer consulting services that relate to the management of customers' business practices** because the customer is ultimately responsible for seeking that advice and in many cases paying for the service.
>
> **If a company were to provide advice, it could be considered a kickback because it could offset the normal overhead expenses for the practice as well as expose our company to potential legal liability.**

(Emphasis added).

149. Janssen's parent JNJ has also acknowledged that providing practice management services to induce sales of its products is inappropriate and unethical when it agreed to abide by the Pharmaceutical Research and Manufacturers of America's Code on Interactions With Health Care Professionals, which includes the following provisions among others:

> Providing items for health care professionals' use that do not advance disease or treatment education — even if they are practice-related items of minimal value

> (such as pens, note pads, mugs and similar "reminder" items with company or product logos) — may foster misperceptions that company interactions with health care professionals are not based on informing them about medical and scientific issues. **Such non-educational items should not be offered to health care professionals or members of their staff, even if they are accompanied by patient or physician educational materials.**
>
> * * *
>
> **No … support, consulting contracts, or educational or practice related items should be provided or offered to a health care professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional's prescribing practices.**

Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (Jan. 2009) at §§ 10, 11 & 13.[15]

E. Janssen Employs a Pricing Strategy that Steers Medicare and Medicaid Infusions Away from Hospitals and Toward Its Top Rheumatology and Gastroenterology Practice Accounts

150. Inasmuch as private practices that have in-office infusion suites are the biggest purchasers of Remicade and Simponi ARIA, Janssen ensures that this market has the best price incentives. Through its CPP program discussed in Part V-A-3 above Janssen offers volume based discounts to physician practices that buy Remicade and Simponi ARIA directly from the Company. The CPP has been highly successful in inducing physician practices to prescribe Remicade and Simponi ARIA rather than other drugs and to buy these drugs directly from Janssen so they can receive the highest profit margin on each vial.

151. Moreover, to keep Remicade's and Simponi ARIA's Average Sales Prices substantially higher than the discounted prices physician practices pay for Remicade and Simponi ARIA under the CPP and thereby ensure that these key customers receive a significant

[15] The Pharmaceutical Research and Manufacturers of America, also known as "PhRMA," is a trade group that is operated by pharmaceutical companies, including JNJ.

profit on each vial of Remicade and Simponi ARIA purchased, Janssen does not offer the volume based discounts to hospitals and other customers, which represent a smaller market for Remicade and Simponi ARIA, and instead charges them full price for the drugs.

152. Since most of Remicade and Simponi ARIA sales are made to physician practices at discounted rates, the Average Sales Prices are usually lower than hospitals' acquisition cost for Remicade and Simponi ARIA. After the infusion service fee, hospitals typically break even on infusions of Remicade and Simponi ARIA to Medicare and Medicaid patients. Because commercial payers generally pay hospitals higher reimbursements for the drugs and the infusion services than Medicare and Medicaid, hospitals normally earn a profit when infusing Remicade and Simponi ARIA to patients with private health insurance.

153. Troublingly, after setting prices at levels that make it unattractive for hospitals to administer Remicade and Simponi ARIA infusions to Medicare and Medicaid beneficiaries, Janssen then advises hospitals to refer these infusion cases to local gastroenterology or rheumatology practices, most of which are Janssen customers or "business partners," and to only provide infusion services to patients covered by commercial payers. Many hospitals have followed Janssen's advice and now refer Medicare and Medicaid infusion cases to local gastroenterology and rheumatology practices, which helps Janssen because the physician practices have a financial incentive to ensure that these patients continue receiving Remicade or Simponi ARIA.[16] Tellingly, Janssen instructs ABSs not to put in writing any of the advice the Company provides to hospitals concerning shedding Medicare and Medicaid infusion cases.

[16] Other hospitals have instead opted to open infusion suites off of the hospital campus. Of course, Janssen assists these hospitals open and operate these infusion suites to ensure that they continue to offer infusion services. Here again, Janssen does not charge the hospital accounts for this valuable business advice and assistance.

F. Janssen Does Not Take into Account the Price-Reducing Effect of the Free Practice Management Services that it Provides When Reporting Remicade's and Simponi ARIA's "Average Sales Price" and "Best Price"

1. *Janssen reports inflated Average Sales Prices for Remicade and Simponi ARIA*

154. Since 2005, Medicare Part B has based reimbursement for physician-administered drugs, including Remicade and Simponi ARIA, on a drug's "Average Sales Price" ("ASP"). (*See* paragraph 93 above).

155. Under the ASP system, within 30 days after the close of each quarter, a drug manufacturer must report to CMS the manufacturer's ASP "to all purchasers" (with certain exceptions) for each of its drugs. *See* 42 U.S.C. §§ 1396r-8(b)(3)(a)(iii) & 1395w-3a(c)(1).

156. Congress and HHS have specifically directed that, "[i]n calculating the manufacturer's average sales price …, such price shall include volume discounts, prompt pay discounts, cash discounts, [and] free goods that are contingent on any purchase requirement …." 42 U.S.C. § 1395w-3a(c)(3); 42 C.F.R. § 414.804(a)

157. If a manufacturer misrepresents the ASP for a drug or biological, the Secretary of HHS may apply a civil monetary penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied. *See* 42 U.S.C. § 1395w-3a(d)(4); 42 C.F.R. § 414.806.

158. When a physician submits a Medicare claim for a drug for which payment is made under the ASP system, Medicare reimburses the physician based on the product's Healthcare Common Procedure Coding System ("HCPCS") code.

159. The amount of reimbursement for a particular HCPCS code is typically 106% of the volume-weighted average of the reported ASPs for the drugs assigned such code during the quarterly period two quarters prior to when the drug for which payment is sought was

administered – *e.g.*, the reimbursement amount for Remicade in the third quarter of 2015 was based on the ASP Janssen reported for Remicade for the first quarter of 2015. *See* 42 U.S.C. § 1395w-3a(b)(l).

160. Consequently, if a manufacturer reports an ASP that does not take into account the price-reducing effect of providing free services contingent on a purchase, the reimbursement amount assigned to the HCPCS will be inflated and Medicare Part B will pay more than it should for all claims for reimbursement for the drugs associated with such HCPCS.

161. Since 2005, Janssen knowingly submitted inflated quarterly ASP reports to CMS concerning Remicade. Likewise, since 2013, Janssen knowingly submitted inflated quarterly ASP reports to CMS concerning Simponi ARIA. Janssen's quarterly ASP reports for these drugs were false because Janssen did not subtract the value of the free practice management services it provided to physician practices. These false ASP reports in turn caused Medicare and Medicaid to pay inflated reimbursement amounts for Remicade and Simponi ARIA, and have rendered false all claims for reimbursement for Remicade and Simponi ARIA presented to Medicare and the state Medicaid programs that reimburse for these drugs based on the ASP system.

2. *Janssen reports inflated Best Prices for Remicade and Simponi ARIA*

162. In 1990, Congress reviewed the prices that Medicaid was paying for prescription drugs and determined that it was routinely paying more than other large drug purchasers for prescription drugs, particularly for "single source drugs," such as Remicade and Simponi ARIA, that are protected by patent. *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Congress also determined that, in order to contain surging drug costs, state Medicaid programs were denying beneficiaries access to needed drugs. *See* 136 Cong. Rec. S12954-01, at *S12955 (Sept. 12, 1990). Believing that Medicaid should receive the benefit of

the same discounts on single source drugs that other large purchasers enjoy, Congress established a rebate mechanism designed to ensure that Medicaid receives the best price for which a manufacturer sells a drug to any purchaser. *See* 1990 U.S.C.C.A.N. at 2108.

163. Under the Medicaid Drug Rebate Statute, each drug manufacturer must enter into a Rebate Agreement with the Secretary of HHS in order for its covered outpatient drugs to be eligible for federal payment under Medicaid. *See* 42 U.S.C. § 1396r-8(a)(1). Under the Medicaid Drug Rebate Statute and the Rebate Agreement, a manufacturer of a brand name drug, such as Remicade and Simponi ARIA, has two primary obligations:

(1) It must report on a quarterly basis to the Secretary the drug's AMP and its Best Price (*see* 42 U.S.C. § 1396r-8(b)(3)(A)); and

(2) It must pay each state a quarterly rebate equal to the total number of drug units purchased by the state times the greater of (a) 15.1% of the drug's AMP, or (b) the difference between the AMP and the Best Price (*see* 42 U.S.C. § 1396r-8(c)(1)(A)).

164. Based on the manufacturer's reported AMP and Best Price, the Secretary, through CMS, computes the unit rebate amount ("URA"). The states then use the URA to invoice the manufacturer for the rebate based upon the state's utilization of the drug. *See* Rebate Agreement at I(dd). Any rebate amount paid by a manufacturer to a state reduces the amount spent by the state and likewise reduces the medical assistance that the federal government provides to the state. *See* 42 U.S.C. § 1396r-8(b)(1)(B).

165. The Medicaid Drug Rebate Statute defines Best Price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, [or] nonprofit entity . . . within the United States." 42 U.S.C. § 1396r-8(c)(1)(C)(i). Physicians and physician practices are types of "providers," and Best Price must take into account prices offered to physicians and physician practices.

166. The Medicaid Drug Rebate Statute provides that a manufacturer's reported Best Price for a drug must take into account "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates …." 42 U.S.C. §§ 1396r-8(c)(1)(C)(ii)(I). In addition, HHS has directed that Best Price is "net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, … incentives, … and any other discounts or price reductions …." 42 C.F.R. § 447.505(e)(1) (2015).

167. Importantly, the Rebate Agreement provides that, in the absence of guidance, a manufacturer may make reasonable assumptions in calculating its Best Price, but that those assumptions must be consistent with the Medicaid Drug Rebate Statute and the Rebate Agreement and must be documented in either a written or electronic record. *See* Rebate Agreement at II(i). The Rebate Agreement further provides that any ambiguities "shall be interpreted in the manner which best effectuates the statutory scheme." Rebate Agreement at IX(e).

168. By providing the various free business advisory and practice management services detailed above, Janssen effectively lowered physician practices' net acquisition cost of Remicade and Simponi ARIA.

169. The Rebate Agreement mandates that Best Price must be adjusted when "other arrangements subsequently adjust the prices actually realized." Rebate Agreement at I(d). HHS has also created a regulation prohibiting drug manufacturers from reallocating discounts to artificially inflate a reported Best Price: "The manufacturer must adjust the best price for a rebate period if … other arrangements subsequently adjust the prices available from the manufacturer." 42 C.F.R. § 447.505(e)(3) (2015).

170. When reporting the Best Price for Remicade and Simponi ARIA to the Secretary each quarter, Janssen did not reduce the price to take into account the value of all of the practice management and business advisory services it provided to rheumatology and gastroenterology practices with in-office infusion suites.

171. By reporting false and inflated Best Prices for Remicade and Simponi ARIA to the Secretary of HHS, Janssen: (1) caused the Secretary to underreport unit rebate amounts to the states, (2) caused the states to seek less in rebates than they were entitled to from Janssen, (3) caused Janssen to pay less in rebates than it actually owed, and (4) caused the federal government to pay more than it should have in federal financial participation funds to the states.

172. As a result of its fraudulent conduct, Janssen saved itself – and took from the Medicaid program – millions of dollars each quarter for nearly a decade.

3. *After completing sales of Remicade and Simponi ARIA to physician practices under the Contract Purchase Program, Janssen adjusts prices to avoid setting a new Best Price for the drugs in violation of the Medicaid Drug Rebate Statute*

173. Moreover, the CPP agreement contains a provision specifically designed to allow Janssen to conceal that it has set new Best Prices for Remicade and Simponi ARIA. More particularly, when the price a physician practice pays for these drugs under the CPP sets a new Best Price, Janssen masks these Best Price sales by reallocating part of the discount to a later purchase transaction, such that the price now appears to be 0.1% more than the price Janssen wants to report to government as being Remicade's or Simponi ARIA's Best Price. Appended below is the discount shifting provision that Janssen uses to manipulate "Best Prices" and pay lower rebates to the state Medicaid programs than should be paid, which correspondingly causes the federal government to pay more than it otherwise would to cover its portion of the costs of Remicade and Simponi ARIA under the state Medicaid programs:

> If the price of any Product, after all price concessions and applicable fees are deducted, is less than the then-current Medicaid "Best Price" threshold, the price concession will be adjusted so that the price of that Product, after the price concession is adjusted, is 0.1% more than the then-current Medicaid "Best Price" threshold. If any price concession is reduced after purchase or after it has been paid, the Company may at its discretion set off the amount of that reduction against any amounts owed to the Customer by the Company under this agreement or request that the Customer pay the Company the amount of that reduction by check or by electronic transfer to an account designated by the Company, in which case the Customer shall pay the Company the amount of that reduction promptly after the Company requests that it do so.

CPP Agreement.

174. As stated above, the Rebate Agreement mandates that Best Price must be adjusted when "other arrangements subsequently adjust the prices actually realized." Rebate Agreement at I(d). HHS has also created a regulation prohibiting drug manufacturers from reallocating discounts to artificially inflate a reported Best Price: "The manufacturer must adjust the best price for a rebate period if … other arrangements subsequently adjust the prices available from the manufacturer." 42 C.F.R. § 447.505(e)(3) (2015).

175. When reporting the Best Price for Remicade and Simponi ARIA to the Secretary each quarter, Janssen did not reduce the price to take into account the value of all of the practice management and business advisory services it provided to rheumatology and gastroenterology practices with in-office infusion suites.

176. Accordingly, Janssen has been knowingly making false records or statements to the United States and Plaintiff States by reporting inflated Best Prices to the Secretary. Janssen did so knowing that the United States and Plaintiff States would rely upon its reported "Best Price" to determine whether Janssen fully paid its statutory rebate obligations, and that by failing to report its "Best Price" the United States and Plaintiff States would have no means of determining that Janssen underpaid rebates to the United States and Plaintiff States. As a result,

Janssen also knowingly failed to pay the full rebate due and owing to the respective states administering the Medicaid program, which correspondingly caused the federal government to pay more than it otherwise would have to cover its portion of the cost of Remicade and Simponi ARIA under the Medicaid program.

177. By reporting false and inflated Best Prices for Remicade and Simponi ARIA to the Secretary, Janssen: (1) caused the Secretary to underreport unit rebate amounts to the states, (2) caused the states to seek less in rebates than they were entitled to from Janssen, (3) caused Janssen to pay less in rebates than it actually owed, and (4) caused the federal government to pay more than it should have in federal financial participation funds to the states.

178. As a result of its fraudulent conduct, Janssen saved itself – and took from the Medicaid program – millions of dollars each quarter for nearly a decade.

VI. COUNTS

Count I
Federal False Claims Act
31 U.S.C. § 3729(a)(1) (*Before May 20, 2009*)
31 U.S.C. § 3729(a)(1)(A) (*On or After May 20, 2009*)

179. This is a claim for treble damages and civil penalties against Janssen under the Federal FCA, 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*), for knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval to the United States and/or, pursuant to 31 U.S.C. § 3729(b)(2)(A)(ii) (*May 20, 2009 and beyond*), to any state Medicaid program.

180. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

181. As a result of its offering and paying kickbacks to induce health care providers to purchase, order, or recommend the purchasing or ordering of Remicade and Simponi ARIA as

well as infusion services to administer the drugs in violation of the Federal AKS, 42 U.S.C. § 1320a-7b(b), and State AKS, Janssen caused the health care providers to present claims for reimbursement to Medicare and the state Medicaid programs that were false or fraudulent because the providers violated the Federal AKS and State AKS by accepting the kickbacks from Janssen.

182. Janssen violated 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*) because through these acts it knowingly caused health care providers who accepted Janssen's kickbacks to present false or fraudulent claims to Medicare for reimbursement for Remicade and Simponi ARIA as well as infusion services provided to Medicare beneficiaries.

183. Janssen also violated 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*) because through these acts it knowingly caused healthcare providers who accepted Janssen's kickbacks to present false or fraudulent claims to the state Medicaid programs for reimbursement for Remicade and Simponi ARIA as well as infusion services provided to Medicaid beneficiaries. Accordingly, Janssen also caused the state Medicaid programs to submit false claims to the United States for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*).

184. In addition, Janssen presented false quarterly submissions to CMS concerning Remicade's and Simponi ARIA's Best Prices. As a result of these false submissions, Janssen knowingly caused the states to present false and inflated claims for Medicaid payments to the United States in violation of 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*).

185. Janssen knowingly caused health care providers and others to present false claims to Medicare for payment for Remicade and Simponi ARIA at fraudulently inflated Average Sales Price rates in violation of 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*).

186. Janssen also violated 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*) because it knowingly caused healthcare providers and others to present false claims to the state Medicaid programs for payment for Remicade and Simponi ARIA at fraudulently inflated Average Sales Price rates. Accordingly, Janssen also caused the state Medicaid programs to submit false claims to the United States for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*).

187. And Janssen violated 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*) because through these acts it knowingly caused others to present, under 31 U.S.C. § 3729(b)(2)(A)(ii), false or fraudulent claims to the state Medicaid programs (grantees and/or recipients of United States funds) for reimbursement for Remicade and Simponi ARIA as well as infusion services provided to Medicaid beneficiaries.

188. The United States, unaware of the foregoing circumstances and conduct, and in reliance on the truth and accuracy of the claims for payment, paid or authorized payment of those claims and has been damaged in an amount to be proven at trial.

Count II
Federal False Claims Act
31 U.S.C. § 3729(a)(2) (*Before June 7, 2008*)
31 U.S.C. § 3729(a)(1)(B) (*On or After June 7, 2008*)

189. This is a claim for treble damages and civil penalties against Janssen under the Federal FCA, 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and 31 U.S.C. § 3729(a)(1)(B) (*June 7,*

2008 and beyond), for knowingly making, using, or causing to be made or used, a false record or statement to get – or that was material to – false or fraudulent claims paid or approved by the United States and/or, pursuant to 31 U.S.C. § 3729(b)(2)(A)(ii) (*May 20, 2009 and beyond*), to any state Medicaid program.

190. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

191. As a result of its offering and paying kickbacks to induce health care providers to purchase, order, or recommend the purchasing or ordering of Remicade and Simponi ARIA as well as infusion services to administer the drugs in violation of the Federal AKS, 42 U.S.C. § 1320a-7b(b), and State AKS, Janssen caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare and Medicaid.

192. More specifically, the health care providers falsely certified, stated, and/or represented that the reimbursements they sought for Remicade and Simponi ARIA as well as infusion services to administer the drugs were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including, but not limited to, the Federal AKS and State AKS. The health care providers' false certifications, statements, or representations caused Medicare and Medicaid to pay out sums that would not have been paid if those programs had been made aware of the falsity of the health care providers' certifications, statements, or representations.

193. Accordingly, Janssen knowingly caused the making or use of false records or statements (a) to get paid (*pre-June 7, 2008*), and/or (b) that were material to (*June 7, 2008 and beyond*) the false or fraudulent claims submitted to the United States for reimbursement for

Remicade and Simponi ARIA as well as infusion services to administer the drugs that were provided to Medicare beneficiaries.

194. Janssen also violated 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*) because through these acts it knowingly caused the making or use of false records or statements (a) to get paid (*pre-June 7, 2008*), and/or (b) that were material to (*June 7, 2008 and beyond*) the false or fraudulent claims health care providers submitted to the state Medicaid programs for reimbursement for Remicade and Simponi ARIA as well as infusion services to administer the drugs that were provided to Medicaid beneficiaries. Accordingly, Janssen also caused the state Medicaid programs to submit false or fraudulent submissions to the United States for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*).

195. Janssen also violated 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*) because through these acts it knowingly made, used, or caused to be made or used, a false record or statement material to false or fraudulent claims under 31 U.S.C. § 3729(b)(2)(A)(ii) submitted by health care providers to the state Medicaid programs (grantees and/or recipients of United States funds) for reimbursement for Remicade and Simponi ARIA as well as infusion services to administer the drugs that were provided to Medicaid beneficiaries.

196. In addition, Janssen has knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by the United States in violation of 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*). Specifically, Janssen knowingly submitted false quarterly statements to CMS concerning the Best Prices for Remicade and Simponi ARIA to

improperly reduce its rebate obligations to the state Medicaid programs under the Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8. Janssen's false quarterly statements concerning the Best Prices for Remicade and Simponi ARIA caused the state Medicaid programs to submit false and inflated submissions to the United States for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*).

197. Janssen has likewise knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by the United States in violation of 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*). Specifically, Janssen knowingly submitted false quarterly statements to CMS of its Average Sales Prices for Remicade and Simponi ARIA, causing the United States to pay more than it should have for all claims for reimbursement for Remicade and Simponi ARIA that are based on the ASP system. Janssen's false quarterly statements of its Average Sales Prices for Remicade and Simponi ARIA also caused the state Medicaid programs to submit false and inflated submissions to the United States for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*).

198. The United States, unaware of the foregoing circumstances and conduct, and in reliance on the truth and accuracy of the claims for payment, paid or authorized payment of those claims and has been damaged in an amount to be proven at trial.

Count III
Federal False Claims Act
31 U.S.C. § 3729(a)(7) (*Before May 20, 2009*)
31 U.S.C. § 3729(a)(1)(G) (*On or After May 20, 2009*)

199. This is a claim for treble damages and civil penalties against Janssen under the Federal FCA, 31 U.S.C. § 3729(a)(7) (*pre-May 20, 2009*) and 31 U.S.C. § 3729(a)(1)(G) (*May 20, 2009 and beyond*), for knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the United States, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the United States and states.

200. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

201. Janssen knowingly made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease obligations to pay or transmit money or property to the government. Janssen was aware of its obligation under the Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8, to make and to use truthful records or statements regarding the Best Prices for Remicade and Simponi ARIA. Janssen also knew that its Best Price submissions would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Janssen was obligated to pay to the state Medicaid programs for Remicade and Simponi ARIA.

202. Janssen knowingly made, used, or caused to be made or used, false records or statements regarding its Best Prices for Remicade and Simponi ARIA in order to conceal, avoid, or decrease its obligations to pay or transmit money or property to the state Medicaid programs, which are jointly funded by the United States and the states, thus directly resulting in significant financial loss to the United States and the states.

203. By virtue of the false records or statements Janssen made, used, or caused to be made or used, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count IV
California False Claims Act
Cal. Gov't Code §§ 12651(a)(1), (2) & (7)

204. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

205. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Cal. Gov't Code § 12651(a)(1).

206. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Cal. Gov't Code § 12651(a)(2).

207. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state …, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state …" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Cal. Gov't Code § 12651(a)(7).

208. The State of California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and

continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

209. By reason of Janssen's acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count V
Colorado Medicaid False Claims Act
Colo. Rev. Stat. §§ 25.5-4-305(1)(a), (b) & (f)

210. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

211. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Colo. Rev. Stat. § 25.5-4-305(1)(a).

212. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b).

213. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state …, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the State …" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Colo. Rev. Stat. § 25.5-4-305(1)(f).

214. The State of Colorado, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

215. By reason of Janssen's acts, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Colo. Rev. Stat. § 25.5-4-305(1), the State of Colorado is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count VI
Connecticut False Claims Act
Conn. Gen. Stat. §§ 4-275(a)(1), (2), (7) & (8)

216. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

217. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval …" in violation of Conn. Gen. Stat. § 4-275(a)(1).

218. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d] or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim …" in violation of Conn. Gen. Stat. § 4-275(a)(2).

219. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d] or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the state … [or] [k]nowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state …" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi

ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Conn. Gen. Stat. §§ 4-275(a)(7) & (8).

220. The State of Connecticut, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

221. By reason of Janssen's acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Conn. Gen. Stat. § 4-275(b), the State of Connecticut is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count VII
Delaware False Claims and Reporting Act
Del. Code tit. 6, §§ 1201(a)(1), (2) & (7)

222. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

223. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Del. Code tit. 6, § 1201(a)(1).

224. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Del. Code tit. 6, § 1201(a)(2).

225. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money … to the Government, or knowingly conceal[ed] or knowingly and improperly

avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the Government" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Del. Code tit. 6, § 1201(a)(7).

226. The State of Delaware, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

227. By reason of Janssen's acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Del. Code tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count VIII
District of Columbia False Claims Act
D.C. Code §§ 2-381.02(a)(1), (2) & (6)

228. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

229. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of D.C. Code § 2-381.02(a)(1).

230. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of D.C. Code § 2-381.02(a)(2).

231. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the District, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the District" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of D.C. Code § 2-381.02(a)(6).

232. The District of Columbia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

233. By reason of Janssen's acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to D.C. Code § 2-381.02(a), the District of Columbia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count IX
Florida False Claims Act
Fla. Stat. §§ 68.082(2)(a), (b) & (g)

234. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

235. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Fla. Stat. § 68.082(2)(a).

236. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d] or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Fla. Stat. § 68.082(2)(b).

237. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money … to the state, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Fla. Stat. § 68.082(2)(g).

238. The State of Florida, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

239. By reason of Janssen's acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Fla. Stat. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count X
Georgia State False Medicaid Claims Act
Ga. Code §§ 49-4-168.1(a)(1), (2) & (7)

240. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

241. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval" in violation of Ga. Code § 49-4-168.1(a)(1).

242. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Ga. Code § 49-4-168.1(a)(2).

243. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Georgia Medicaid program, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the Georgia Medicaid program" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Ga. Code § 49-4-168.1(a)(7).

244. The State of Georgia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

245. By reason of Janssen's acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Ga. Code § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XI
Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21(a)(1), (2) & (6)

246. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

247. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Haw. Rev. Stat. § 661-21(a)(1).

248. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Haw. Rev. Stat. § 661-21(a)(2).

249. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the State" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Haw. Rev. Stat. § 661-21(a)(6).

250. The State of Hawaii, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for the acts and conduct of Janssen alleged herein.

251. By reason of Janssen's acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XII
Illinois False Claims Act
740 Ill. Comp. Stat. 175/3(a)(1)(A), (B) & (G)

252. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

253. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

254. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

255. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the State, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the State" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

256. The State of Illinois, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

257. By reason of Janssen's acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to 740 Ill. Comp. Stat. 175/3(a)(1), the State of Illinois is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XIII
Indiana False Claims & Whistleblower Protection Act
Ind. Code §§ 5-11-5.5-2(b)(1), (2), (6) & (8) (*Before and On June 30, 2014*)
Ind. Code §§ 5-11-5.7-2(a)(1), (2), (6) & (8) (*After June 30, 2014*)

258. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

259. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Ind. Code §§ 5-11-5.7-2(a)(1) & (8) and Ind. Code §§ 5-11-5.5-2(b)(1) & (8) (*before and on June 30, 2014*).

260. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Ind. Code §§ 5-11-5.7-2(a)(2) & (8) and Ind. Code §§ 5-11-5.5-2(b)(2) & (8) (*before and on June 30, 2014*).

261. By virtue of the acts described above, Janssen "[k]knowingly (A) ma[de], use[d], or cause[d] to be made or used, a false record or statement concerning an obligation to pay or transmit money … to the state; or (B) conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money … to the state" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Ind. Code §§ 5-11-5.7-2(a)(6) & (8) and Ind. Code §§ 5-11-5.5-2(b)(6) & (8) (*before and on June 30, 2014*).

262. The State of Indiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

263. By reason of Janssen's acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Ind. Code § 5-11-5.7-2(a), the State of Indiana is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XIV
Iowa False Claims Act
Iowa Code §§ 685.2(1)(a), (b) & (g)

264. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

265. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Iowa Code § 685.2(1)(a).

266. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Iowa Code § 685.2(1)(b).

267. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the state or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Iowa Code § 685.2(1)(g).

268. The State of Iowa, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

269. By reason of Janssen's acts, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Iowa Code § 685.2(1), the State of Iowa is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XV
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §§ 46:438.3(A), (B) & (C)

270. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

271. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim" in violation of La. Rev. Stat. § 46:438.3(A).

272. By virtue of the acts described above, Janssen "[k]nowingly engage[d] in misrepresentation or ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of La. Rev. Stat. § 46:438.3(B).

273. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the medical assistance programs, or … knowingly conceal[ed], avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the medical assistance programs" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of La. Rev. Stat. § 46:438.3(C).

274. The State of Louisiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

275. By reason of Janssen's acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to La. Rev.

Stat. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XVI
Maryland False Health Claims Act
Md. Code, Health-General §§ 2-602(a)(1), (2), (7) & (8)

276. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

277. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Md. Code, Health-General § 2-602(a)(1).

278. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Md. Code, Health-General § 2-602(a)(2).

279. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the State … [or] [k]nowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the State" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Md. Code, Health-General §§ 2-602(a)(7) & (8).

280. The State of Maryland, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

281. By reason of Janssen's acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Md. Code, Health-General § 2-602(b)(1), the State of Maryland is entitled to three times the amount of actual damages plus a penalty of not more than $10,000 per violation.

Count XVII
Massachusetts False Claims Law
Mass. Laws. ch. 12, §§ 5B(a)(1), (2) & (9)

282. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

283. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Mass. Laws. ch. 12, § 5B(a)(1).

284. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Mass. Laws. ch. 12, § 5B(a)(2).

285. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money … to the Commonwealth …, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the Commonwealth …" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Mass. Laws. ch. 12, § 5B(a)(9).

286. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen,

paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

287. By reason of Janssen's acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mass. Laws. ch. 12, § 5B(a), the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XVIII
Michigan Medicaid False Claims Act
Mich. Comp. Laws §§ 400.607(1) & (3)

288. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

289. By virtue of the acts described above, Janssen "ma[de] or present[ed] or cause[d] to be made or presented to an employee or officer of this state a claim under the social welfare act … upon or against the state, knowing the claim to be false" in violation of Mich. Comp. Laws § 400.607(1).

290. By virtue of the acts described above, Janssen "knowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money … to the state pertaining to a claim presented under the social welfare act" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Mich. Comp. Laws § 400.607(3).

291. The State of Michigan, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and

continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

292. By reason of Janssen's acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mich. Comp. Laws § 400.612, the State of Michigan is entitled to three times the amount of actual damages plus a penalty of $5,000 to $10,000 per violation.

Count XIX
Minnesota False Claims Act
Minn. Stat. §§ 15C.02(a)(1), (2) & (7)

293. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

294. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Minn. Stat. § 15C.02(a)(1).

295. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Minn. Stat. § 15C.02(a)(2).

296. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the state or a political subdivision, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state or a political subdivision" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Minn. Stat. § 15C.02(a)(7).

297. The State of Minnesota, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

298. By reason of Janssen's acts, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Minn. Stat. § 15C.02(a), the State of Minnesota is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XX
Montana False Claims Act
Mont. Code §§ 17-8-403(1)(a), (b) & (g)

299. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

300. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Mont. Code § 17-8-403(1)(a).

301. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Mont. Code § 17-8-403(1)(b).

302. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to an obligation to pay or transmit money … to a governmental entity or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to a governmental entity" specifically when reporting Best Price information and paying rebates concerning

Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Mont. Code § 17-8-403(1)(g).

303. The State of Montana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

304. By reason of Janssen's acts, the State of Montana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mont. Code § 17-8-403, the State of Montana is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXI
Nevada False Claims Act
Nev. Rev. Stat. §§ 357.040(1)(a), (b), (f) & (g)

305. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

306. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Nev. Rev. Stat. § 357.040(1)(a).

307. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Nev. Rev. Stat. § 357.040(1)(b).

308. By virtue of the acts described above, Janssen "[k]nowingly ma[de] or use[d], or cause[d] to be made or used, a false record or statement that is material to an obligation to pay or transmit money … to the State or a political subdivision … [or] [k]nowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money … to

the State or a political subdivision" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Nev. Rev. Stat. §§ 357.040(1)(f) and (g).

309. The State of Nevada, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

310. By reason of Janssen's acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Nev. Rev. Stat. § 357.040(2), the State of Nevada is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XXII
New Jersey False Claims Act
N.J. Stat. §§ 2A:32C-3(a), (b) & (g)

311. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

312. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval" in violation of N.J. Stat. § 2A:32C-3(a).

313. By virtue of the acts described above, Janssen "[k]nowingly make[d], use[d], or cause[d] to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State" in violation of N.J. Stat. § 2A:32C-3(b).

314. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to conceal, avoid or decrease an

obligation to pay or transmit money … to the State" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of N.J. Stat. § 2A:32C-3(g).

315. The State of New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

316. By reason of Janssen's acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.J. Stat. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XXIII
New Mexico Medicaid False Claims Act
N.M. Stat. §§ 27-14-4(A), (C) & (E)

317. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

318. By virtue of the acts described above, Janssen "present[ed], or cause[d] to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent" in violation of N.M. Stat. § 27-14-4(A).

319. By virtue of the acts described above, Janssen "ma[de], use[d] or cause[d] to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false" in violation of N.M. Stat. § 27-14-4(C).

320. By virtue of the acts described above, Janssen "ma[de], use[d] or cause[d] to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money … to the state, relative to the medicaid program, knowing that such record or statement is false" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of N.M. Stat. § 27-14-4(E).

321. The State of New Mexico, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

322. By reason of Janssen's acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.M. Stat. § 27-14-4, the State of New Mexico is entitled to three times the amount of actual damages.

Count XXIV
New York False Claims Act
N.Y. State Fin. Law §§ 189(1)(a), (b), (g) & (h)

323. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

324. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of N.Y. State Fin. Law § 189(1)(a).

325. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of N.Y. State Fin. Law § 189(1)(b).

326. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the state … [or] knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state …" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of N.Y. State Fin. Law §§ 189(1)(g) and (h).

327. The State of New York, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

328. By reason of Janssen's acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.Y. State Fin. Law § 189(1), the State of New York is entitled to three times the amount of actual damages plus a penalty of $6,000 to $12,000 per violation.

Count XXV
North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-607(a)(1), (2) & (7)

329. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

330. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of N.C. Gen. Stat. § 1-607(a)(1).

331. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of N.C. Gen. Stat. § 1-607(a)(2).

332. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the State, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the State" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of N.C. Gen. Stat. § 1-607(a)(7).

333. The State of North Carolina, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

334. By reason of Janssen's acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.C. Gen. Stat. § 1-607(a), the State of North Carolina is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXVI
Oklahoma Medicaid False Claims Act
63 Okl. St. §§ 5053.1(B)(1), (2) & (7)

335. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

336. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval" in violation of 63 Okl. St. § 5053.1(B)(1).

337. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved the state" in violation of 63 Okl. St. § 5053.1(B)(2).

338. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money … to the state" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of 63 Okl. St. § 5053.1(B)(7).

339. The State of Oklahoma, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

340. By reason of Janssen's acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to 63 Okl. St. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus a penalty of $5,000 to $10,000 per violation.

Count XXVII
Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1-3(a)(1), (2) & (7)

341. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

342. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

343. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

344. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the state, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money or property to the state" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

345. The State of Rhode Island, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

346. By reason of Janssen's acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to R.I. Gen. Laws § 9-1.1-3(a), the State of Rhode Island is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXVIII
Tennessee Medicaid False Claims Act
Tenn. Code §§ 71-5-182(a)(1)(A), (B) & (D)

347. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

348. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval under the medicaid program" in violation of Tenn. Code § 71-5-182(a)(1)(A).

349. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program" in violation of Tenn. Code § 71-5-182(a)(1)(B).

350. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the state, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the state, relative to the medicaid program" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Tenn. Code § 71-5-182(a)(1)(D).

351. The State of Tennessee, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

352. By reason of Janssen's acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Tenn.

Code §§71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus a penalty of $5,000 to $25,000 per violation.

Count XXIX
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code §§ 36.002(1), (5), (12) & (13)

353. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

354. By virtue of the acts described above, Janssen "knowingly ma[de] or cause[d] to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized" in violation of Tex. Hum. Res. Code § 36.002(1).

355. By virtue of the acts described above, Janssen "knowingly pa[id], … solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, … or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program" in violation of Tex. Hum. Res. Code § 36.002(5).

356. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money or property to this State under the Medicaid program" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Tex. Hum. Res. Code § 36.002(12).

357. By virtue of the acts described above, Janssen "knowingly engage[d] in conduct that constitutes a violation under Section 32.039(b) [prohibiting kickbacks]" in violation of Tex. Hum. Res. Code § 36.002(13).

358. The State of Texas, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

359. By reason of Janssen's acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Tex. Hum. Res. Code § 36.052(a)(3), the State of Texas is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXX
Vermont False Claims Act
32 V.S.A. §§ 631(a)(1), (2), (9) & (10)

360. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

361. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of 32 V.S.A. § 631(a)(1).

362. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of 32 V.S.A. § 631(a)(2).

363. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the State … [or] knowingly conceal[ed] or knowingly and improperly

avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the State" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of 32 V.S.A. §§ 631(a)(9) & (10).

364. The State of Vermont, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

365. By reason of Janssen's acts, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to 32 V.S.A. §§ 631(b)(1) & (2), the State of Vermont is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XXXI
Virginia Fraud Against Taxpayers Act
Va. Code §§ 8.01-216.3(A)(1), (2) & (7)

366. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

367. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Va. Code§ 8.01-216.3(A)(l).

368. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Va. Code § 8.01-216.3(A)(2).

369. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceal[ed] or knowingly and

improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money or property to the Commonwealth" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Va. Code § 8.01-216.3(A)(7).

370. The Commonwealth of Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

371. By reason of Janssen's acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXXII
Washington Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.020(1)(a), (b) & (g)

372. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

373. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Wash. Rev. Code § 74.66.020(1)(a).

374. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Wash. Rev. Code § 74.66.020(1)(b).

375. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money … to the government entity, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money … to the government entity" specifically when reporting Best Price information and paying rebates concerning Remicade and Simponi ARIA in violation of 42 U.S.C. § 1396r-8, all in violation of Wash. Rev. Code § 74.66.020(1)(g).

376. The State of Washington, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

377. By reason of Janssen's acts, the State of Washington has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Wash. Rev. Code § 74.66.020(1), the State of Washington is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

PRAYER FOR RELIEF

WHEREFORE, Relator demands that judgment be entered in favor of the United States and the Plaintiff States and against Janssen for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the federal FCA, three times the amount of damages to the United States plus civil penalties of no more than $11,000 and no less than $5,500 for each false claim before or on November 1, 2015, and civil penalties of no more than $21,563 and no less than $10,781 for each violation after November 2, 2015, and any other recoveries or relief provided for under the Federal FCA. This

Request also includes, with respect to the Plaintiff States' false claims act statutes, the maximum damages, the maximum fines or penalties, and any other recoveries or relief provided for or permitted by those state statutes.

Further, Relator requests that they receive the maximum amount permitted by law from the proceeds or settlement of this action as well as from any alternative remedies collected by the United States and the Plaintiff States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that their award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities who are not parties to this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

DATED: October 27, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I will cause a copy of the above Complaint to be served on the following counsel by certified mail, return receipt requested:

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DATED: October 27, 2016

Casey M. Preston